UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* VINCENT R. TURANO, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN and the DISTRICT OF COLUMBIA, *Plaintiffs*, v. ELI LILLY AND COMPANY, *Defendant*.	**COMPLAINT** Civil Action No. **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
UNDER 31 U.S.C. § 3729 *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by Vincent R. Turano, by and through his attorneys, against Defendant Eli Lilly and Company pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *et seq.*; the Colorado Medicaid False Claims Act, COLO. REV. STAT. § 25.5-4-304 (2010) *et seq.*; the Connecticut False Claims Act, 2009 CONN. PUB. ACTS NO. 09-5 (Sept. Spec. Sess.), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.;* the Florida False Claims Act, FLA. STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN.§ 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act. HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE § 5-11-5.5, (2007) *et seq.*, the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.;* the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A), (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Minnesota False Claims Act, MINN. STAT. § 15C.01 *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 (2005), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 265 (2007); the New Mexico Medicaid False Claims Act,

N.M. STAT. ANN. § 27-14-1 (2007), *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605, *et. seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*, and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.*, ("State *qui tam* statutes" or "*Qui Tam* States").

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant and/or its agents, employees or co-conspirators under the Federal False Claims Act and the State *qui tam* statutes.

2. Defendant Eli Lilly and Company ("Lilly") is a company that manufactures, markets, and sells a variety of drugs for medicinal purposes. In recent years, the company has faced significant pressure to generate new sources of revenue, and to expand revenues from existing sources, because its three top selling drugs (Zyprexa®, Cymbalta® and Humalog®), which comprise 46% of Lilly's 2009 revenues, will lose patent protection between 2011 and 2014. In all, five of Lilly's seven top-selling drugs (add Gemzar® and Evista® to the list) will lose patent protection by 2014. Together, these five drugs comprise 57% of Lilly's worldwide revenue. To make matters worse for the company, Lilly recently lost a patent case that could lead to early generic competition for Strattera®, a drug that contributed an additional $609.4 million to Lilly's 2009 worldwide revenues.

3. The loss of patent protection generally results in new competition from generic drug manufacturers, resulting in a substantial loss of revenue. In all, Lilly projects that "eight significant products, which together comprise 74% of [the company's] worldwide revenue, will lose their most significant remaining U.S. patent protection, as well as their intellectual property-based exclusivity in most countries outside the U.S. in the next several years[.]" The pending loss of such a substantial percentage of worldwide revenue is a significant problem for Lilly. *See* Eli Lilly & Company, Annual Report (Form 10-K), at 11-12 (Feb. 22, 2010). (Lilly's financial prospects took another hit when, on August 17, 2010, the company announced that it would halt development of semagacestat, its once promising treatment for Alzheimer's disease.)

4. In an effort to mitigate the anticipated loss of revenue from its top selling drugs, Lilly embarked upon an aggressive (and illegal) scheme to (i) expand off-label sales of Gemzar® (gemcitabine), and (ii) increase revenues from sales of another drug, Alimta® (pemetrexed), through an illegal, off-label promotion scheme.

5. Gemzar® is a chemotherapy drug that initially was approved by the Food and Drug Administration ("FDA") in 1996 for the treatment of pancreatic cancer. It was approved in 1998 for the treatment of non-small cell lung cancer, and subsequently received limited approvals for the treatment of pancreatic cancer, advanced ovarian cancer, and breast cancer. Following a recent decision of the U.S. Court of Appeals for the Ninth Circuit, Gemzar® will lose its patent exclusivity later this year. As described more fully below, Lilly has anticipated this problem for some time, and designed its fraudulent marketing scheme in order to (i) illegally promote Gemzar® for *unapproved* uses in combination with the generic drug docetaxel (a/k/a Taxotere®), and (ii) illegally transition as much on- and off-label use of Gemzar® as possible to Lilly's newer patent-protected chemotherapy drug, Alimta®.

6. Alimta® is a chemotherapy drug that has been approved by the FDA for only four narrowly-defined treatment protocols, two of which were not approved by the FDA until 2008. Despite the unambiguous limitations imposed by the FDA, however, Lilly devised and deployed a fraudulent marketing scheme that was intended to and did systematically and illegally promote the use of Alimta® as part of *unapproved* combination therapies with a generic drug called carboplatin in lieu of equally or more effective *approved* combination carboplatin therapy utilizing a drug called paclitaxel (a/k/a Taxol®), which has been available in generic form since 2000, instead of Alimta®.

7. Key to Lilly's fraudulent scheme has been the understanding that cancer patients are desperate for a cure and their physicians are eager to provide one. Lilly also has understood from the beginning that many cancer patients are Government Program beneficiaries, such that most of the cost of their chemotherapy regimens will be borne by the Federal and State Governments. The fraudulent marketing scheme described herein was designed to capitalize on this desperation of patients and eagerness of physicians, who Lilly intended and expected would submit false and fraudulent claims for reimbursement of off-label uses of Gemzar® and Alimta® by Government Programs such as Medicare Part B and Part D.

8. Further compounding its offense, Lilly has illegally induced healthcare professionals to prescribe the *unapproved* Gemzar®/docetaxel combination for the treatment of metastatic breast cancer, and the *unapproved* Alimta®/carboplatin combination, in lieu of the less expensive, but equally or more effective *approved* combinations, this time preying not upon the patients' fear, but upon healthcare professionals' greed.

9. Lilly's illegal, off-label promotion of Gemzar® and Alimta® has caused hundreds of thousands of false claims to be submitted to Federal and State healthcare programs throughout

the United States. Lilly's misconduct cheated the Federal and State governments out of hundreds of millions of dollars that should not have been paid, thereby illegally enriching Lilly at taxpayer expense, and subjecting patients to unapproved, ineffective and unsafe uses of Gemzar® and Alimta®. Lilly's illegal conduct began at least as early as 2004, and it continues to this day.

10. Lilly continued to carry out its fraudulent marketing scheme even while it was negotiating a settlement and plea in connection with the Zyprexa® investigation, and Lilly has continued to pursue that scheme even after agreeing in 2009 to pay $1.415 billion to settle civil and criminal charges that it illegally promoted Zyprexa® off-label. As part of the settlement with the Federal Government and several states, Lilly entered into a Corporate Integrity Agreement whereby it pledged, among other things, to cease all further off-label marketing. Ironically, the desperation and greed that led Lilly to illegally promote Gemzar® and Alimta® is not unlike the desperation and greed that led Lilly to illegally promote Zyprexa® to replace the lost revenue when its former bestseller, Prozac®, lost patent protection.

II. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331 and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

12. This Court has personal jurisdiction over the Defendant because, among other things, the Defendant transacts business in this District, and engaged in wrongdoing in this District.

13. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). The Defendant transacts business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

14. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendant to conceal from the United States its wrongdoing in connection with the allegations made herein.

III. PARTIES

A. PLAINTIFF/RELATOR VINCENT R. TURANO

15. Plaintiff/Relator Vincent R. Turano ("Relator Turano") is a resident of the State of New York. He received his Bachelor of Science degree from the University of the State of New York, Excelsior College, in 2000, and he received a Master of Public Administration in Healthcare degree from Long Island University, C.W. Post, in 2005. He is a former member of the American College of Healthcare Executives and the Oncology Nursing Society.

16. Relator Turano has been employed by the Defendant in its Oncology Division since March 2005 (although he was on a medical leave of absence from July 30, 2009 until February 1, 2010, and again from April 5, 2010 to May 24, 2010). Initially, Relator Turano was hired as a Senior Sales Specialist, but he later was promoted to Executive Sales Specialist. In these positions, he has been, and continues to be, charged with promoting Gemzar® and Alimta® within his assigned geographic territory, which until March 31, 2010 included all of Suffolk County, New York and most of Nassau County, New York. Since April 1, 2010, Relator Turano's territory has included North Nassau County and Queens, New York. At all times relevant to this Complaint, Relator Turano's immediate supervisor at Lilly was (and continues to be) Senior Oncology District Manager Michael S. Polkowitz.

17. Prior to joining Lilly, Relator Turano worked as an Account Manager for BioScrip from mid-November 2004 to April 2005, and as a Senior Oncology Specialty Consultant for Pfizer Inc./Pharmacia Corporation from May 2000 to mid-November 2004. Prior to joining Pfizer/Pharmacia, Relator Turano worked for Novartis Pharmaceuticals Corporation as a Territory Manager from December 1995 to December 1996, as an Institutional Specialist from January 1997 to February 1998, and as an Oncology Sales Specialist from March 1998 to April 2000.

18. Relator Turano is an original source of the off-label promotion allegations in this Complaint, and these allegations are not based upon publicly disclosed information. He has provided the government with material information prior to the filing of this Complaint in accordance with 31 U.S.C. § 3730(b)(2).

19. Prior to filing this Complaint, Relator Turano brought the wrongdoing described in this Complaint to the attention of Lilly by raising his concerns directly with Lilly Oncology Trainer Lee Thomas during his initial training with the company, and by repeatedly raising his concerns with his supervisor, Lilly Oncology District Manager Michael Polkowitz. Both of these individuals rejected Relator Turano's concerns and instead, through their words and their actions, sent a clear message to Relator Turano that he would be fired if he pursued his complaints any further, or if he failed to aid and abet the company's off-label promotional efforts, described *infra*. Lending credibility to this threat, Relator Turano is not aware of a single instance in which a Lilly sales representative was fired for initiating or failing to report off-label promotion, though he repeatedly has observed such conduct by his supervisor, DM Polkowitz, and his sales representative colleagues. (Mr. Thomas now is a District Manager for Lilly's Oncology Division, and he is based in the Boston area.)

B. DEFENDANT ELI LILLY AND COMPANY

20. Eli Lilly and Company (NYSE:LLY) ("Eli Lilly" or "Lilly") is an Indiana corporation with its principal place of business located in Indianapolis, Indiana. Lilly employs approximately 39,000 people throughout the world. Lilly is the tenth largest pharmaceutical company in the world, with net sales in 2009 of $21.8 billion, and net income in 2009 of $4.3 billion.

21. As described more fully herein, Lilly is engaged in the manufacture, promotion, distribution, commercialization and sale of products for, among other things, oncology therapies. Throughout the relevant period, Lilly marketed and sold substantial quantities of its pharmaceutical products, including Gemzar® and Alimta®, in the State of New York and in the United States.

22. Lilly markets and sells, and marketed and sold, brand-name prescription drug products, including Gemzar® and Alimta®, that are paid or reimbursed by various governmental programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association ("BCBSA"), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.* via Medicare Part C, (also known as Medicare+Choice), Medicare Part B, Medicare Advantage, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE") and the Veteran's Health Administration ("VHA") (collectively, the "Federal Programs").

23. On January 15, 2009, Lilly agreed to settle another "off-label" promotion case with the U.S. Department of Justice for a record-setting $1.415 billion. *See* discussion *supra.* It was at the time the largest amount ever paid by a single defendant in Department of Justice history.

24. As a result of Lilly's actions, the *Qui Tam* States and Federal Programs have suffered significant financial harm.

IV. SUMMARY OF DEFENDANT'S ILLEGAL CONDUCT

A. THE PURPOSE, MANNER AND MEANS OF THE FRAUDULENT MARKETING SCHEME

25. Lilly's objective in implementing the Fraudulent Marketing Scheme was to increase sales of Gemzar® and Alimta®, both organically and, in the case of Alimta®, by stealing market share from the generic drug paclitaxel. Lilly also intended that its scheme would aid the company in converting healthcare professionals' use of Gemzar® over to Alimta® once Gemzar® lost patent exclusivity in the fourth quarter of 2010.

26. Lilly pursued its Fraudulent Marketing Scheme by routinely and intentionally directing its substantial sales force to illegally promote the use of Gemzar® for unapproved uses in combination with docetaxel for the treatment of breast cancer, and to illegally promote the use of Alimta® in lieu of paclitaxel, and in combination with Avastin®, by initiating discussions with and among health care professionals about this *unapproved* combination therapy. Additionally, Lilly trained and directed its sales representatives to use volumetric financial incentives provided by Lilly's contracts with various group purchasing organizations to further promote the off-label sales and use of Alimta®.

27. Lilly intended that, by training, instructing, and deploying its sales representatives to promote Gemzar® and Alimta® as part of unapproved combination therapies in lieu of less expensive approved combination therapies, its Fraudulent Marketing Scheme would cause false and fraudulent statements to be made, and cause false and fraudulent claims to be submitted for payment by Government Programs. These claims were paid, permitting Lilly to maximize profits through its ill-gotten gains.

28. Lilly's Fraudulent Marketing Scheme was designed (and deployed) in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* and its state analogues.

29. Lilly's unlawful off-label promotion of Gemzar® and Alimta® involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims.

30. Lilly's conduct had a material effect on the Governments' decision to pay for Gemzar® and Alimta®. Had the Federal Government and *Qui Tam* States known that the off-label prescriptions were the direct and intended result of Lilly's unlawful activities, they would not have made such reimbursements, or they would have reimbursed substantially lesser amounts.

31. It further was part of the Fraudulent Marketing Scheme that Lilly attempted to conceal and cover up the off-label marketing of Gemzar® and Alimta®.

32. Lilly's perpetration of the Fraudulent Marketing Scheme is ongoing.

B. LILLY'S DEALS WITH GROUP PURCHASING ORGANIZATIONS DRIVE OFF-LABEL SALES

33. Unlike many other prescription drugs, Gemzar® and Alimta® are administered intravenously in a physician's office or outpatient clinic. In these cases, the physician first purchases the drug from Lilly or a wholesaler, and then seeks reimbursement from an insurer or Government Program by billing under a J-Code (discussed below). The amount that is not reimbursed by insurance or a Government Program is then billed to the patient.

34. Group Purchasing Organizations ("GPOs") are organizations that, among other things, negotiate discounted drug acquisition rates with manufacturers and wholesalers on behalf of their member physicians and healthcare providers. Some GPOs simply manage or provide access to a discounted, wholesale drug acquisition process, while other GPOs operate their own wholesale drug dispensaries.

35. Over time, due to the special market forces present and the significant monetary opportunities presented, oncology GPOs have become a major market force. These oncology GPOs contract with networks of oncologists as part of strategic alliances. In addition to offering practice management and other services, the primary service these oncology GPOs offer is contracting for market differentiated pricing with drug companies like Lilly. Three primary GPOs have emerged and dominate the oncology market through their contracted networks of oncologists: (i) ION, which is owned by drug wholesaler giant AmeriSourceBergen, "controls" about 50% of the oncology market; (ii) US Oncology controls about 20% of the oncology market; and (iii) Onmark, which is owned by drug wholesaler McKesson, controls about 30% of the oncology market.

36. The oncology GPOs also have created clinical "pathways," which are treatment algorithms that determine which oncology drugs will be used, and in what doses. In this way, the oncology GPOs drive the course of oncology treatment. Upon treating a patient with

Gemzar® or Alimta®, the health care professional submits a claim for reimbursement to the patient's insurer or, in the case of Government Program beneficiaries, to the Government Program. The patient is then responsible for payment of the co-payment or co-insurance amount.

37. As described more fully below, it was the plan and purpose of Lilly's Fraudulent Marketing Scheme to utilize the tiered volume discounts provided to physicians and clinics through their oncology GPO contracts to improperly incentivize them to prescribe Gemzar® and Alimta® as part of *unapproved* combination therapies, in lieu of *approved* combination therapies that were equally (or more) effective, and less expensive. The oncology GPO deals thereby led physicians to prescribe Lilly's more expensive drugs off-label, in lieu of less expensive drugs on-label, which improperly increased costs for Government Programs.

38. As Gemzar® approached the loss of patent protection, Lilly also improperly used its oncology GPO contracts to "bundle" Gemzar® with Alimta®, promising healthcare providers that if they would prescribe greater volumes of Gemzar®, those prescriptions would count towards their volume discount thresholds for Alimta®.

39. Lilly's conduct had a material effect on the Governments' decision to pay for Gemzar® and Alimta®. Had the Federal Government and *Qui Tam* States known that the off-label prescriptions were the direct and intended result of Lilly's unlawful leveraging of financial incentives to induce off-label usage of the drugs, they would not have made such reimbursements.

V. BACKGROUND OF THE REGULATORY FRAMEWORK

A. THE FOOD AND DRUG ADMINISTRATION ("FDA") REGULATORY SYSTEM

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed

40. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

41. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

42. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

43. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical

investigations" has been interpreted to mean a clinical study with (i) clear objectives; (ii) adequate design to permit a valid comparison with a control group; (iii) adequate selection of study subjects; (iv) adequate measures to minimize bias; and (v) well defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

44. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998. *See, e.g.,* Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979). The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, the FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, the FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different endpoints, to support a single adequate

and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

45. In other cases, the FDA has relied on only a single, adequate and well-controlled efficacy study to support approval – generally only in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed the FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

46. Cases in which the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multicenter trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug

development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

47. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off-Label Marketing and False and Misleading Statements About a Drug's Use

48. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels – including all marketing and promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

49. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

50. A manufacturer, like Lilly, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

51. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved to treat adults.

52. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug

makers, drug company sponsored continuing medical education ("CME") courses and speaker programs, and drug company sponsored clinical trials.

53. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

54. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below.

55. Title 21 of the Code of Federal Regulations provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." 21 C.F.R. 202.1(e)(6)(xi); *see also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution of a misbranded drug); *id.* § 360aaa

(permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

56. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6) *et seq.* ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Lilly may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Government Programs, including Medicaid.

57. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. 202.1(e)(6)(iv).

58. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. 202.1(e)(5) *et seq.* A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

59. Title 21 of the Code of Federal Regulations broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug. 21 C.F.R. 202.1(1)(2)

60. Title 21 also requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." 21 C.F.R. 201.56.

61. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

62. These regulations lay out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. 21 C.F.R. 99.101 *et seq*. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

63. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

64. And off-label information may be disseminated only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

65. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. And the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA Has Limited Ability To Regulate Marketing and Promotion

66. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

67. DDMAC's effectiveness in regulating off-label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if at all, only after the materials already

have appeared in public. *See* Woodcock Statement, *supra.* Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

68. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

69. The FDA's ineffectiveness in policing off-label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf. Among the Report's findings: (1) the FDA does not have separate oversight activities to specifically capture off-label promotion; (2) the FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (3) the FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (4) the FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives; and (5) during calendar years 2003 through 2007, the FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

B. THE ROLE OF THE COMPENDIA

70. Congress has adopted a Compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." *See* Social Security Act §§ 1927(g)(1)(B)(i) and (k)(6). The statute permits reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."

71. Pursuant to its statutory authority, the Centers for Medicare and Medicaid Services ("CMS") further define the circumstances under which a prescription for off-label use of an oncology drug can be reimbursed under Medicaid, Medicare or the other Government Programs. Since June 1, 2008, CMS has recognized four so-called "Compendia" to be used in determining whether drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen are to be considered as being medically accepted. *See, e.g.*, Medicare Benefit Policy Manual (the "Policy Manual"), Ch. 15, Sec. 50.4.4. Those Compendia are the American Hospital Formulary Service Drug Information ("AHFS"), the National Comprehensive Cancer Network ("NCCN"), Thomson Micromedex DrugDex ("DRUGDEX"), and Clinical Pharmacology.

72. Prior to June 1, 2008, CMS recognized only AHFS, and two now defunct Compendia called American Medical Association Drug Evaluations ("AMA-DE") and United States Pharmacopeia-Drug Information ("USP-DI").

73. Mere citation in the Compendia does not qualify a use as "medically accepted." Because the Compendia employ various ratings and recommendation systems that "may not be readily cross-walked from Compendium to Compendium," CMS provides a two-part test to determine whether an off-label use identified by one of the Compendia is "medically accepted"

for reimbursement purposes. Specifically, coverage is not to be denied solely on the basis that use of the drug is "off-label" as long as (i) the use is supported by any of the Compendia; and (ii) the use "is **not** listed as unsupported, not indicated, not recommended, or equivalent terms" in any of the other Compendia. *See* CMS Policy Manual, Ch. 15, Sec. 50.4.5(B) (emphasis in original). Thus, for an off-label use to be reimbursable by Government Programs, it must not only be supported by any one of the Compendia, but it also must **not** be listed as not supported by any one of the other Compendia. If even one of the Compendia identifies a use as not medically accepted, then use fails the conjunctive test and it is not reimbursable under the Government Programs.

74. The Policy Manual further explains what constitutes a supported or "medically accepted" use and what defines an unsupported or "not medically accepted" use. For instance, a use is considered "medically accepted" if the indication is: (i) a Category 1 or 2A in NCCN; (ii) a Class I, IIa, or Class IIb in DRUGDEX; or (iii) the narrative text in AHFS or Clinical Pharmacology is supportive. Alternatively, a use is "not medically accepted" by a Compendium if the indication is: (i) a Category 3 in NCCN; (ii) a Class III in DRUGDEX; or (iii) the narrative text in AHFS or Clinical Pharmacology is "not supportive." The Policy Manual adds that the complete absence of a narrative text on a particular use is considered neither supportive nor non-supportive.

75. Moreover, whether a particular use is "supported by" a Compendium citation may depend on a variety of factors, including the type of drug and indication at issue, the content of the Compendium citation, and the scope and outcome of the studies cited and described in the Compendium. Thus, it is appropriate in determining whether a particular use is reimbursable to

"look behind" the applicable Compendium citation to evaluate the character and reliability of the study or studies upon which it is based.

76. It merits emphasis that even where an off-label use is supported by the Compendia, drug companies may not legally promote that use to healthcare professionals or patients.

C. FEDERAL HEALTH CARE PROGRAMS AND OTHER GOVERNMENT PROGRAMS

1. The Medicaid Program

77. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

78. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2)-(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* § 1396r-8(k)(3).

79. A medically-accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug Compendia identified in the Medicaid statute. *Id.* § 1396r-8(k)(6); *see* discussion *supra*. During the time period relevant to this Complaint, Lilly promoted off-label uses of Gemzar® and Alimta® that were not eligible for reimbursement from Medicaid because the off-label uses were neither listed in the FDA-approved labeling nor adequately supported by the effective drug Compendia specified by the Medicaid statute.

2. The Medicare Program

80. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

81. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k), as described above.

82. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

83. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135% of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

84. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies.

85. The Medicare Modernization Act of 2003 ("MMA") attempted to modernize reimbursement for cancer drugs and essential cancer-care services by reforming the payment systems for oncology. Under the MMA, reimbursement for cancer drugs changed from the "average wholesale price" to a system based on average selling price ("ASP"). Now, a physician who purchases and administers a cancer drug to a Medicare Part B beneficiary in his office generally is eligible to be reimbursed up to 106% of the ASP of that drug, but 106% of an expensive branded drug, such as Gemzar® or Alimta®, is more than 106% of a less expensive generic drug.

86. During the time period relevant to this Complaint, Lilly promoted off-label uses of Alimta® that were not eligible for reimbursement from Medicare because the off-label uses were neither listed in the FDA-approved labeling nor adequately supported by the effective drug Compendia specified by the statute.

3. Reimbursement Under Other Federal Health Care Programs

87. In addition to Medicaid and Medicare, the Federal Government reimburses a portion of the cost of prescription drugs under several other federal health care programs. For example:

(i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.

(ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100% service-connected disabilities.

(iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid program. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

88. When a healthcare provider seeks reimbursement from Medicare, it first identifies the particular reimbursement code for the drug prescribed. These reimbursement codes are a component of the CMS Healthcare Common Procedure Coding System ("HCPCS"). The HCPCS is designed to bill for drugs that are utilized in the physician's office, clinic or home health agency. Under this classification scheme, most covered drugs are assigned J-codes, which are permanent codes used to identify injectable drugs that ordinarily cannot be self-administered, as well as some oral anti-cancer drugs. The J-Code for Gemzar® is J9201, and the J-Code for Alimta® is J9305.

89. Gemzar® and Alimta® can also be dispensed at pharmacies for patients with a prescription. Pharmacies seek reimbursement from Medicare based on a drug's National Drug Code ("NDC") number. The NDC codes for Gemzar® are:

Gemzar® NDC Codes

Package Strength	Code
200 mg / 10 mL vial	0002-7501-01
1 g / 50 mL vial	0002-7502-01

90. The NDC codes for Alimta® are:

Alimta® NDC Codes

Package Strength	Code
100 mg	0002-7640-01
500 mg	0002-7623-01

91. During the time period relevant to this Complaint, Lilly promoted off-label uses of Gemzar® and Alimta® that were not eligible for reimbursement under any of the various Federal health care programs.

VI. BACKGROUND OF GEMZAR® AND ALIMTA®

A. THE OFF-LABEL USE OF ONCOLOGY DRUGS

92. A 1991 survey by the Government Accountability Office showed that 56 percent of oncology patients received at least one off-label drug during the course of their cancer treatments. That trend has continued. A 2006 report by the American Society of Clinical Oncology noted that approximately half of the prescriptions for oncology drugs are for uses that have not been approved by the FDA. *See* "Reimbursement of cancer treatment: coverage of off-label drug indications," 24 J. CLIN. ONCOL. 3206–3207 (2006). Even though many drugs are

commonly prescribed by physicians for off-label treatments, as discussed above, pharmaceutical companies are not allowed to promote these indications. If it becomes evident through pharmaceutical research and/or from common medical practice that a drug's off-label indications might be beneficial, drug manufacturers must submit a Supplemental New Drug Application to the FDA before they can begin promoting the indications. Because off-label indications often have not been subject to rigorous testing in clinical trials, allowing pharmaceutical companies to promote off-label use of their drugs would compromise existing statutory and regulatory safety nets.

93. Off-label use of oncology drugs is widespread. The largest, most carefully conducted analysis of outpatient prescribing patterns found that 21 percent of prescribed medications are used for non-FDA-approved indications. Among medications used off-label, 73 percent lacked evidence of clinical efficacy and only 27 percent were supported by strong scientific evidence. *See* Radley, *et al.*, "Off-label prescribing among office-based physicians," 166 ARCHIVES OF INTERNAL MED. 1021-1026 (2006).

94. Other studies suggest an even greater prevalence of off-label prescribing in oncology. For example, an in-depth study of the monoclonal antibody rituximab at an academic medical center over three years found that 75 percent of the uses of the drug were off-label. *See* Kocs, *et al.*, "Effect of off-label use of oncology drugs on pharmaceutical costs: the rituximab experience," 9 AM. J. MANAGED CARE 393-400 (2003). Another recent study found that the five most widely-prescribed chemotherapeutic agents were used for off-label indications in 50 percent of cases. *See* Eastman, *et. al.*, "Reimbursement policies discourage off-label drug use," 27 ONCOL. TIMES 8, 10 (2005).

95. Terminally ill cancer patients are particularly vulnerable to promises that unproven treatments will be effective. According to an editorial in the Journal of the American Medical Association:

> Despite the appealing rhetoric of choice and the belief that there is a medical cure for every illness – even at the end of life – public policy must balance the harms and benefits of pharmaceuticals and determine the optimal level of regulation. No one wants to deprive dying patients of access to drugs that may extend their lives. But no one should understate the potential scientific and clinical consequences of removing the FDA's role in monitoring drug safety and effectiveness.

See Jacobson, *et al.*, "A New Era of Unapproved Drugs: The Case of *Abigail Alliance v. Von Eschenbach*," 297 J. AM. MED. ASSOC. 205-08 (2007).

96. Most oncologists in the United States derive a large majority of their income directly from the drugs they prescribe. This money from the drugs they prescribe creates an incentive that encourages use of costly treatments that may offer only marginal value to patients. While oncologists may bristle at the notion that profits from drugs influence their treatment recommendations, most economists find it hard to believe basic principles of economic theory vanish in cancer care. Indeed, recent data suggest that reimbursement does influence oncologists' prescribing choices, at least for Medicare beneficiaries. *See* Jacobson, *et al.*, "Does reimbursement influence chemotherapy treatment for cancer patients?" 25 HEALTH AFFAIRS 437-443 (2006). Oncologists are loath to acknowledge that financial motives can affect treatment decisions. Although reimbursement seems to have little effect on the oncologist's primary decision to administer palliative chemotherapy to patients with advanced solid tumors, it appears to affect the choice of drugs used. *Id.* at 442. Once a decision to give chemotherapy was taken, physicians used more costly treatment regimens. *Id.* This tendency for oncologists to prescribe

the more expensive drug feeds into the drug company's desire to push untested medications off-label in lieu of less expensive, on-label treatments.

97. A pharmaceutical company like Lilly has a strong self-interest in coming to market with a new drug as soon as possible in order to have maximum benefit from remaining patent protection and thereby refinance the high cost of drug development. Like most pharmaceutical companies, Lilly is a publicly-traded corporation whose primary aim is to increase profits and shareholder value. Thus, its economic self-interest lies in quickly obtaining a single FDA-approved indication for a new drug like Alimta®, so that it can get the drug into the marketplace as quickly as possible and then manipulate that marketplace so that the drug also will be prescribed for a wide range of unapproved uses. The Fraudulent Marketing Scheme described in this Complaint were born from these circumstances.

B. FDA AND COMPENDIA APPROVALS OF GEMZAR®

98. Gemzar® was first approved by the FDA on August 25, 1998 to be used in combination with another drug, cisplatin (which belongs to the class of drugs known as "platinum" drugs), for the treatment of patients with inoperable, locally advanced or metastatic non-small cell lung cancer. Several years later, the FDA approved Gemzar® (i) as a single-agent (*i.e.*, not in combination with another drug) first-line treatment for patients with locally advanced or metastatic pancreatic cancer, or for patients previously treated with 5-fluorouracil; (ii) in combination with paclitaxel for the first-line treatment of metastatic breast cancer (with certain preconditions); and (iii) in combination with carboplatin for patients with advanced ovarian cancer who relapse at least six months after platinum-based therapy. Gemzar® has not been approved by the FDA for any other use, and so its FDA-approval is limited as follows:

Approval Date	Scope of Approval
May 15, 1996	Approved as a single-agent, first-line therapy for patients with locally advanced or metastatic pancreatic cancer, or for patients previously treated with 5-fluorouracil.
August 25, 1998	Approved as first-line therapy in combination with cisplatin for patients with inoperable, locally advanced or metastatic non-small cell lung cancer.
May 19, 2004	Approved in combination with paclitaxel for patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.
July 14, 2006	Approved in combination with carboplatin for patients with advanced ovarian cancer who relapse at least six months after platinum-based therapy.

99. Thus, Gemzar® is not FDA-approved for *any* combination therapy with docetaxel.

100. As indicated, Government Programs have, since June 1, 2008, been permitted to reimburse the off-label (*i.e.,* non-FDA-approved) use of Gemzar® if the use in question has the necessary support in the AHFS, DRUGDEX, NCCN or Clinical Pharmacology Compendia, and before then if the use in question had the necessary support in the AHFS, AMA-DE or USP-DI Compendia. Unlike Alimta®, discussed *infra*, there are more than thirty citations for Gemzar® in the various Compendia – suggesting widespread, if unapproved, use among healthcare professionals. However, among all these Compendia citations, only four describe a Gemzar®/docetaxel combination therapy, and as relevant to this Complaint, only one of those citations relates to the treatment of breast cancer:

- As a single agent or in combination with other agents, including vinorelbine, platinum analogs, anthracyclines, and taxanes as doublets or triplets, for the treatment of breast cancer. (Clinical Pharmacology, citing

Silvestris, N. *et al.*, Rationale for the use of gemcitabine in breast cancer (review), INT. J. ONCOL., 24: 389-398, 2004.

Relator Turano is unaware whether either the defunct AMA-DE or USP-DI Compendia purported to support the off-label Gemzar®/docetaxel combination to treat breast cancer.

101. It merits emphasis that, although this use is cited in one of the Compendia, Lilly still was not legally permitted to promote it. Further, as discussed more fully below, the process by which Lilly obtained that Compendium citation was corrupted by Lilly, and thus it should not be considered reliable for reimbursement purposes.

102. Lilly has systematically promoted Gemzar® beyond its relatively narrow FDA approvals and, as a result, off-label sales have been robust and Government Program reimbursements have been significant. Total U.S. sales of Gemzar® since its approval in 1996 have been approximately $6.2 billion, including $363.5 million in the first six months of 2010, and total Medicaid reimbursements during that period have exceeded $158 million. During the first three quarters of 2009 alone, Medicaid reimbursements for Gemzar® were approximately $22 million, reflecting a fifty percent increase over the same period in 2008. With the loss of Gemzar®'s patent exclusivity quickly approaching, Lilly has been anxious to transition those on- and off-label sales to Alimta® (since Alimta® is not scheduled to lose its relevant U.S. Patent protection until 2016).

C. FDA AND COMPENDIA APPROVALS OF ALIMTA®

103. Alimta® was first approved by the FDA on February 4, 2004 to be used in combination with a specific platinum drug, cisplatin, for the treatment of patients with malignant pleural mesothelioma, a type of tumor of the lining of the lung. Later that same year, on August 19, 2004, the FDA approved Alimta® as a single-agent treatment for patients with locally

advanced or metastatic non-small cell lung cancer second-line after prior chemotherapy. Four years later, on September 28, 2008, the FDA supplemented its approval of Alimta® for the treatment of non-small cell lung cancer by approving Alimta® for the treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer (i) as first-line therapy in combination with cisplatin, and (ii) as a single agent for the treatment of patients after prior chemotherapy. The following year, on July 2, 2009, the FDA approved Alimta® as maintenance therapy for patients whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Alimta® has not been approved by the FDA for any other use, and so its FDA-approval is limited as follows:

Approval Date	**Scope of Approval**
February 4, 2004	Approved in combination with cisplatin for the treatment of malignant pleural mesothelioma.
August 19, 2004	Approved as a single-agent for the treatment of locally advanced or metastatic non-small cell lung cancer after prior chemotherapy.
September 28, 2008	Approved for the treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer (i) as first-line therapy in combination with cisplatin, and (ii) as a single agent for the treatment of patients after prior chemotherapy.
July 2, 2009	Approved as maintenance therapy for patients whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

104. Thus, Alimta® was not FDA-approved for *any* combination therapy with carboplatin before July 2, 2009.

105. Among all of the Compendia described *supra*, only three Alimta®/carboplatin combination therapies find any support:

- In combination with carboplatin for the treatment of advanced NSCLC (Clinical Pharmacology, citing Zinner *et al.*, Phase II study of pemetrexed in combination with carboplatin in the first-line treatment of advanced nonsmall cell lung cancer, CANCER, 104(11):2449-56 (2005);

- In combination with cisplatin or carboplatin as first-line therapy for recurrence or metastasis in patients with performance status (PS) 0-2 or elderly patients (NCCN); and

- In combination with cisplatin or carboplatin and bevacizumab (Avastin®) as first-line therapy for recurrence or metastasis in patients with PS 0-1 nonsquamous cell histology and no history of hemoptysis (NCCN).

Relator Turano is unaware whether either the defunct AMA-DE or USP-DI compendia purported to support the off-label Alimta®/carboplatin combination.

106. Again, although these uses are cited in the Compendia, Lilly still was not legally permitted to promote them. Further, as discussed more fully below, the process by which Lilly obtained citations for these uses was corrupted by Lilly, and thus they should not be considered reliable for reimbursement purposes.

107. From the beginning, Lilly's promotional activities have ignored the relatively narrow on-label FDA approvals for Alimta® and, as a result, off-label sales have been robust. Total sales in 2009 alone were $1.71 billion, including approximately $815 million in sales that originated in the United States (an astounding 45 percent increase over the prior year). During the first and second quarters of 2010, U.S. sales were a combined $476.3 million, reflecting increases of 29% and 28%, respectively, over the same periods the prior year – truly a remarkable growth rate that reflects Lilly's off-label promotional efforts described in this Complaint.

108. Even Eli Lilly's CEO, John Lichleiter, acknowledged that its increased sales were due, in part, to off-label use. In the third quarter 2008 earnings call, he told investors:

> With respect to Alimta, I think there is probably... some of that growth probably does reflect use in first line, notwithstanding that we didn't ... we did not begin to promote that obviously until we got the indication, I think at the very end of September. But it's ... clearly, I think the data in the non-squamous histology is going to make Alimta increasingly the drug of choice in treating that type of tumor in the first-line setting.

See Transcript of Eli Lilly & Co. Q3 2008 Earnings Conference Call, *available at*, http://seekingalpha.com/article/101555-eli-lilly-co-q3-2008-earnings-conference-call-transcript? (last visited Aug. 17, 2010).

109. Relator Turano estimates that approximately 40-50 percent of all Alimta® sales are off-label, that approximately 80 percent of those off-label sales are for unapproved combination therapies in which Alimta® is approximately twenty times more expensive than the approved generic alternative, paclitaxel, and that approximately half the off-label sales of Alimta® are reimbursed by Government Programs.

VII. THE FRAUDULENT MARKETING SCHEME

110. At all relevant times, Lilly has known that Gemzar® and Alimta® are being paid for or reimbursed by Government Programs, including Medicaid and Medicare Parts B and D.

111. Lilly knows, or it has been reasonably foreseeable to Lilly, that its promotion of Gemzar® and Alimta® would lead to the submission by health care professionals of Gemzar® and Alimta® prescriptions that, but for its fraud, would have been otherwise ineligible for payment by Government Programs.

112. When Lilly initially decided to employ the illegal practices described herein, it knew (or should have known) that health care professionals would routinely and necessarily file claims with Government Programs for reimbursement for Gemzar® and Alimta® prescriptions. But for Lilly's illegal promotion, these off-label and misbranded prescriptions for Gemzar® and

Alimta® would not have been written. As a result, Lilly has caused, and continues to cause, the submission of false claims to Government Programs for reimbursement of Gemzar® and Alimta®. Lilly has been the beneficiary of these false claims for reimbursement.

A. LILLY ILLEGALLY PROMOTES GEMZAR® FOR OFF-LABEL USE

113. Although it has received only four rather narrow FDA approvals for Gemzar®, Lilly has worked hard to promote the drug for a wide array of other off-label uses, including those cited in the various Compendia. In doing so, Lilly has capitalized on patient fear and desperation, and physicians' willingness to prescribe any drug, regardless of proven efficacy, in part due to the physicians' unique opportunity to profit from chemotherapy drugs.

114. Although Gemzar® is FDA-approved for the treatment of breast cancer in combination with paclitaxel, Lilly long ago understood that oncologists already had a significant level of comfort using docetaxel for the treatment of their breast cancer patients, and that (because docetaxel had become the standard of care) Lilly would have an extraordinarily difficult time persuading physicians to prescribe Gemzar® within its only FDA-approved combination – *i.e.,* with paclitaxel. Accordingly, Lilly has been particularly (and consistently) aggressive about promoting Gemzar® in combination with docetaxel (which doctors are comfortable with) for the treatment of breast cancer.

1. Lilly Instructed Its Sales Representatives to Initiate Off-Label Discussions with Physicians and Health Care Providers

115. In 2004, the FDA approved a Gemzar®/paclitaxel combination for the treatment of metastatic breast cancer. *See* discussion *supra.* At the time, however, the recognized standard of care for the treatment of that condition was Xeloda®/docetaxel. Thus, while Lilly's

registration trial compared Gemzar®/paclitaxel against paclitaxel alone, most physicians viewed the trial as irrelevant and initial sales of Gemzar® for metastatic breast cancer were dismal.

116. In an attempt to propel sales forward, Lilly instructed and trained its sales representatives to become proficient in a "bait and switch" sales tactic by which they would open a sales call with a discussion of the on-label Gemzar®/paclitaxel combination, but then go directly into affirmative promotion of an off-label, multi-page, laminated Medical Reference entitled: "*What data are available on Gemzar® (gemcitabine HCL) in combination with taxanes in the treatment of breast cancer?*" This particular Medical Reference, which sales representatives were required to include "in their bags," purported to provide key information from several Gemzar® studies, including one Phase III study that specifically compared the physician preferred, on-label Xeloda®/docetaxel combination against the unapproved and otherwise unproven Gemzar®/docetaxel combination. *See* Chan, S. *et al.*, Gemcitabine plus docetaxel (GD) versus capecitabine plus docetaxel (CD) for anthracycline-pretreated metastatic breast cancer (MBC) patients (pts): results of a European phase III study; JOURNAL OF CLINICAL ONCOLOGY, 2005 ASCO ANNUAL MEETING PROCEEDINGS, Vol. 23, No. 16S, Part I of II (June 1 Supplement), 2005: 581 (the "Chan Study").

117. The Chan Study demonstrated equal median progression free survival (the primary objective) of 35 weeks in each arm, and equal 32% median overall response rate, but significantly less hand and foot syndrome for those patients taking Gemzar®/docetaxel. (The results of the Chan Study were presented at the 2005 Annual Meeting of the American Society of Clinical Oncology, and the complete presentation and results may be viewed at www.asco.org.) The Chan Study was so important to Lilly's off-label marketing strategy for Gemzar® that the company required sales representatives to take an online examination that included questions

about the Chan Study's conclusions. (A copy of the examination slides is included among the materials provided by Relator Turano to the Government.) Lilly then instructed its sales representatives to aggressively promote the off-label Gemzar®/docetaxel combination to physicians, using the Medical References and Chan Study, and they have done so with great success – despite the fact that long-term efficacy and safety of the Gemzar®/docetaxel combination *still* has not been established.

118. Dr. Hope S. Rugo, a leading breast cancer specialist, has opined that the Chan Study's toxicity comparison was biased towards a positive result for the Gemzar®/docetaxel combination and thus "should be evaluated with caution." *See* Rugo, H.S., Gemcitabine/docetaxel a new treatment option for metastatic breast cancer: Comment, THE ONCOLOGY REPORT, Fall 2005. Nevertheless, Lilly pursued this strategy because it understood that since Gemzar® and docetaxel each were FDA-approved for certain indications, improper claims for reimbursement by Government Programs for their use in combination each other likely would slip through the cracks.

119. During his initial training at Lilly in April 2005, Relator Turano complained to Lilly's Oncology Trainer, Lee Thomas, that the manner in which he was being directed to use the Medical References was improper. Mr. Thomas rejected these concerns, and deliberately embarrassed Relator Turano in front of the training class for having questioned the company's instruction on how to use the Medical References. Several days later, Mr. Thomas insisted that Relator Turano retake a video simulation training test, allegedly because Relator Turano did not adequately use his selling resources. Mr. Turano understood that he was being punished for challenging the company's directive to use the Medical References to initiate off-label promotional discussions.

120. Lilly reinforced its instruction to self-initiate off-label promotion of the Gemzar®/docetaxel combination through "practice selling" workshops, in which the person playing the role of the physician would say: "I don't use [paclitaxel] in combination therapy to treat metastatic breast cancer" and the person assigned to play the role of the sales representative would be instructed to respond by presenting the Medical Reference describing the Chan Study, and then attempting to persuade the physician using the Chan data that the off-label Gemzar®/docetaxel combination had strong efficacy endpoints, was well-tolerated and generally should be prescribed in lieu of the FDA-approved Xeloda®/docetaxel combination. These practice selling workshops were attended by Lilly managers, including DM Polkowitz; thus, Relator Turano understood by the manner in which the workshops were conducted, and the presence of management, that using the Medical References as a means to self-initiate off-label promotion of Gemzar® was a requirement of the job, and that he would be fired if he refused.

121. The sales representatives followed these instructions, with great success. Their use of the Medical References to self-initiate off-label promotion of the Gemzar®/docetaxel combination led to increased Gemzar® utilization by physicians at the following medical practices and institutions, among others:

- Memorial Sloan Kettering Cancer Center in New York City, including satellite clinics in Commack, New York and Rockville Centre, New York;
- North Shore University Hospital in Manhasset, New York, including the Monter Cancer Center in Lake Success, New York;
- Winthrop Oncology Group/Winthrop Hospital in Minneola, New York;
- Hematology Oncology Associates of Western Suffolk in Bay Shore, New York;
- Medical Oncology Associates in Woodbury, New York;

- Huntington Medical Group in Huntington, New York; and
- Tomao, Marino, McNelis, Ginsburg & Chandok Oncology Group in Port Washington, New York.

It merits emphasis that, like most oncology practices, each of these practice groups has a significant population – possibly exceeding 60% – of patients who are Medicare beneficiaries.

2. Lilly Used Paid "Thought Leaders" to Promote Gemzar® Off-Label for the Treatment of Breast Cancer

122. Promotional programs funded and conducted by pharmaceutical companies are highly regulated by the FDA. Essentially, promotional educational presentations must be "on-label," presenting only information about FDA-approved uses contained in the product's package insert. Promotional talks must also contain "fair balance" – *i.e.*, a discussion of the risks and benefits of the drug, including adverse effects, precautions, and warnings. Above all, promotional programs must be truthful and not misleading. All presentation slides, whether provided by the pharmaceutical company or developed by the speaker, should be designed to meet these requirements.

123. A narrow exception to the "on-label" rule exists for promotional programs. Speakers may answer questions about unapproved drug uses so long as the questions posed by the audience are unsolicited. Speakers should clearly advise the audience that the answer is outside the scope of approved labeling and that they are speaking from independent medical judgment. Questions should be answered briefly, to avoid unnecessary off-label discussion, and then the discussion should be guided back to the originally planned, on-label presentation.

124. Lilly has understood that using influential doctors to promote the Gemzar®/docetaxel combination off-label for the treatment of breast cancer could be a very

effective (but illegal) way to grow market share. Thus, Lilly routinely has paid such doctors to give such promotional talks to other healthcare professionals precisely *because* they can be relied upon to *initiate* off-label discussions with members of the audience. Confirming the promotional nature of these talks, Lilly specifically instructs its sales representatives to arrange speaker programs for their large or under-performing accounts, and it only selects speakers that it knows will initiate off-label discussions.

125. Lilly also has used its speaker programs to increase Gemzar® utilization among speakers themselves. Thus, for example. Lilly recruited Dr. Steven Sugarman of the Memorial Sloan Kettering facility in Commack, New York to be a paid speaker for Gemzar® in order to encourage him to begin prescribing Gemzar®, including for off-label purposes, himself. When he still would not prescribe Gemzar® even after delivering approximately ten promotional presentations, Lilly dropped him as a speaker. Similarly, District Manager Polkowitz told Relator Turano to recruit Dr. Jeffrey Schneider of Winthrop Hospital to be a paid speaker in order to increase his utilization of both Gemzar® and Alimta®, but Dr. Schneider declined.

126. But, the primary purpose of paid speaker programs was to use well-respected physicians to persuade their colleagues to prescribe the Gemzar®/docetaxel combination off-label. As described below, Lilly *expected* that the speakers would initiate off-label discussions, and Lilly's sales representatives understood that they were *not* to interrupt those discussions, nor report them to their supervisors, since doing so would limit the effectiveness of the underlying sales pitch, thereby placing their jobs in jeopardy. That District Manager Polkowitz attended many of these off-label presentations and remained silent himself, simply confirmed what Relator Turano already knew: his job was to facilitate the off-label discussions, not prevent

them, and if he did not do his job as expected, he would be fired. Here are non-exclusive examples of speakers Lilly used to promote Gemzar® off-label:

(a) **Dr. Daniel Budman**

127. Lilly paid Dr. Daniel Budman (Monter Cancer Center, 450 Lakeville Road, Lake Success, NY 11042) $3,000.00 to deliver a promotional talk entitled: "*Clinical Discussion on Metastatic Breast Cancer with Slide Presentation*" at Mather Hospital, in Port Jefferson, New York, on or about September 19, 2005. Attendees included Dr. Edward Samuels of North Shore Hematology/Oncology Associates ("NSHOA"). Relator Turano was present at this event, and he observed Dr. Budman initiate an off-label promotion of the Gemzar®/docetaxel combination to treat breast cancer. Relator Turano also observed that Dr. Budman added a large number of his own slides to the presentation. Dr. Budman frequently used his own slides, and always initiated off-label discussions. Relator Turano remained silent because it was clear that he would lose his job if he interfered with the sales pitch.

128. Lilly paid Dr. Budman $3,000 to deliver another promotional talk entitled "*Clinical Discussions in Metastatic Breast Cancer*" on or about December 8, 2006, this time for NSHOA's satellite office in Patchogue, New York. Relator Turano was present at this event. From the start, Dr. Budman's talk ventured into off-label territory, including a discussion with NSHOA's Dr. Nawaz during which Dr. Budman promoted an off-label use of Gemzar® to treat one of Dr. Nawaz's patients. Substitute District Manager Rob Lowe attended this program in DM Polkowitz's stead, and he neither stopped nor reported the off-label conversation to Lilly, nor did he criticize Dr. Budman directly or tell Relator Turano that he should do any of these things. This confirmed for Relator Turano that Lilly expected him to remain silent in the face of off-label promotion.

129. Lilly paid Dr. Budman $3,000.00 (plus expenses) to deliver yet another promotional talk entitled "*Clinical Discussions in Metastatic Breast Cancer*" at Stony Brook University Hospital on or about August 16, 2007. Dr. Janice Lu was one of the attendees. Relator Turano also was present at this event, and he observed Dr. Budman initiate an off-label promotion of the Gemzar®/docetaxel combination to treat breast cancer. Again, Relator Turano remained silent because he knew that he would lose his job if he interfered with the sales pitch.

(b) **Dr. Yelena Novik**

130. Lilly paid Dr. Yelena Novik (NYU Langone Medical Center, 160 East 34th Street, New York, NY 10016) $1,500.00 (plus expenses) to deliver a promotional talk entitled "*Clinical Discussions in Breast Cancer*" on or about May 15, 2007 at the H20 Seafood Grill in Smithtown, New York. From the start, Dr. Novik's talk ventured into the off-label promotion of multiple Gemzar® combinations, including Gemzar®/docetaxel to treat breast cancer. Attendees included Dr. Michael Theodorakis and more than 25 nurses and staff from multiple oncology practice groups (*e.g.,* North Shore Hematology Oncology Associates, Stony Brook University Hospital). DM Polkowitz personally attended this program with Relator Turano, and he neither stopped nor reported the off-label conversation to Lilly, nor did he criticize Dr. Novik, nor did he tell Relator Turano that he should do any of these things.

(c) **Dr. Joyce O'Shaughnessy**

131. Lilly paid Dr. Joyce O'Shaughnessy (Charles A. Sammons Cancer Center, 3535 Worth Street, Dallas, TX 75246) $4,000.00 (plus expenses) to deliver a promotional talk entitled "*Clinical Discussions in Metastatic Breast Cancer*" at North Shore University Hospital on or about December 6, 2006. Relator Turano attended this event with his sales partner. Dr. O'Shaugnessy prepared an elaborate collection of off-label slides and, from the start, ventured

into off-label territory without any prompting. The talk lasted more than two hours, and the attendees included oncology fellows and one or two attending physicians. Relator Turano remained silent (as, apparently, did his sales partner) because it was clear that he would lose his job if he interfered with the sales pitch. According to Lilly's online Faculty Registry, Dr. O'Shaughnessy conducted eight similar speaker programs for Lilly in 2009 alone, and was paid $16,075.00 by Lilly for her speaking activities.

(d) **Dr. Ruth Oratz**

132. Lilly paid Dr. Ruth Oratz (The Women's Oncology & Wellness Practice, 345 East 37th Street, Suite 202, New York, NY 10016) to deliver a promotional talk entitled "*Clinical Discussions in Metastatic Breast Cancer*" at Burton and Doyles Steakhouse in Great Neck, New York on or about June 27, 2007. Relator Turano and his sales partner were present at this event and observed Dr. Oratz initiate the off-label promotion. The program was open to all oncologists, and the off-label discussion was initiated by Dr. Oratz, as Lilly had intended. Attendees included Dr. Steven Savona of North Shore University Hospital and Dr. Tony Cheung of the Queens Long Island Medical Group in Valley Stream, New York. Relator Turano remained silent (as, apparently, did his sales partner) because he understood that he would lose his job if he interfered with the sales pitch.

(e) **Dr. Andrew Seidman**

133. Lilly paid Dr. Andrew Seidman (Memorial Sloan Kettering Cancer Center, 300 East 66th Street, New York, NY 10065) $4,000.00 (plus expenses of $503.78) to deliver a promotional talk entitled "*Clinical Discussions in Metastatic Breast Cancer*" at Stony Brook University Hospital on April 26, 2006. Eight different physicians attended this event: Janice Lu, Gurvi Sethi, Susanna Hong, Ilya Blokh, Eva Chalis, Timothy Pardee, Sarah Vidito and Licheng

Xu. Relator Turano was present at this event and observed Dr. Seidman initiate off-label promotion of the Gemzar®/docetaxel combination to treat breast cancer. He also modified the standard visual presentation to include his own, personal "baked" slides that reflected his personal research and experience, including off-label uses and concepts. Relator Turano remained silent because he understood that he would lose his job if he interfered with the sales pitch. According to Lilly's online Faculty Registry, Dr. Seidman conducted eighteen similar speaker programs for Lilly in 2009 alone, and was paid $53,950.00 by Lilly for his speaking activities.

(f) **Dr. Steven Sugarman**

134. Lilly paid Dr. Steven Sugarman (Memorial Sloan Kettering Cancer Center, 650 Commack Road, Commack, NY 11725) $1,500.00 to deliver a promotional talk entitled: "*New Advances in the Treatment of Metastatic Breast Cancer*" at the H20 Seafood Grill in Smithtown, New York on or about September 15, 2005 for physicians at Stony Brook University. Attendees included Drs. N. Gostanian, Triantafillos Fillos, Susanna Hong, C. Mohin, Ilya Blokh, and Shilen Patel. Relator Turano also was present at this event, and he observed Dr. Sugarman initiate an off-label discussion of the Gemzar®/docetaxel combination to treat breast cancer. Dr. Sugarman also used his own off-label slides as part of the presentation. Relator Turano remained silent because it was clear that he would lose his job if he interfered with the sales pitch.

3. Lilly's Control of the CMEs Transformed Them into Promotional Events for Off-Label Use of Gemzar®

135. Another key source of drug information for doctors is continuing medical education ("CME") courses, usually medical lectures held locally featuring key opinion leaders. Required in order for physicians to maintain their medical licenses and stay current with new

developments and give patients the best medical care, many CME courses provide expert syntheses of clinical trial information.

136. The percentage of CMEs that are commercially funded increased significantly from forty-eight percent in 1998 to fifty-eight percent in 2002. Currently, sixty percent of CMEs have direct commercial sponsorship; indirect sponsorship (*e.g.,* via non-profits funded by company money) accounts for a large portion of the remainder. Total industry contributions towards continuing medical education is estimated to be seventy percent or higher and total in the hundreds of millions of dollars.

137. The content of the CME programs is intended to be independent of drug companies. According to FDA guidance, independent educational grants cannot be tied to the purchase, sale, prescription, or recommendation of the company's products. *See* Guidance Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64093 (Dec. 3, 1997). There cannot be price concessions to help offset a customer's purchase or reimbursement of drugs, and there cannot be any payment to ensure that the grant recipient markets the company's drugs during the educational program. Grants provided to customers of a pharmaceutical company (institutional pharmacies, retail chain pharmacies, pharmacy benefit managers, managed care organizations, and others) must be especially focused on educating health care professionals in order to avoid any appearance of price concession or quid pro quo arrangement. *Id.* Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belong solely to the CME provider in accordance with their guidelines. *Id.*

138. According to Lilly's policy concerning educational grants, "Lilly upholds the highest standards in the way we conduct business. Therefore, when we respond to requests for

grants and contributions, the policies and procedures we follow are designed to assure that there is no inappropriate influence by the Company on the content or balance of educational programs, and that all grants and contributions are made in full compliance with applicable laws and regulations." *See* http://www.lillygrantoffice.com/pages/grant_registry.aspx (last visited Aug. 17, 2010).

139. Lilly violated the FDA guidance and its own policies governing CME events when it manipulated the CME programs into events that promoted off-label uses of Gemzar®. For example, Lilly funded a CME program entitled "*Phase III Study Of Gemcitabine Plus Docetaxel Versus Capecitabine Plus Docetaxel for Anthracycline-Pretreated Metastatic Breast Cancer Patients: Survival Results for Anthracycline-Pretreated Metastatic Breast Cancer*" at the San Antonio Breast Cancer Conference held December 13-16, 2007. As intended by Lilly, this CME actively promoted the off-label use of Gemzar® in combination with docetaxel to treat breast cancer.

B. LILLY ILLEGALLY PROMOTES ALIMTA® FOR OFF-LABEL USE

140. To Lilly's chagrin, the Alimta®/cisplatin combination therapy that was approved by the FDA in 2004 initially captured only a relatively small percentage of the thoracic (lung) cancer market. At the time, most oncologists had a long-standing comfort and familiarity with a different combination therapy – paclitaxel/carboplatin, which had been available in generic form since 2000 – for the same patient population. Accordingly, despite actual knowledge that it was prohibited by Federal law from promoting off-label uses of Alimta®, Lilly has, from the outset, sought to expand its share of the market by instructing its sales force to promote various off-label uses of Alimta®, including that Alimta®/carboplatin combination in lieu of the less expensive paclitaxel/carboplatin regimen. And, with the emergence of a new FDA-approved regimen that

combines the paclitaxel/carboplatin therapy with Avastin® (manufactured by Genentech), Lilly has instructed its sales force to refer to the paclitaxel/carboplatin component of that regimen as the "backbone" therapy, and to encourage physicians to replace the paclitaxel/carboplatin component with Alimta® and either cisplatin or carboplatin for their patients.

141. Contrary to the message being delivered by Lilly, there is no evidence that Alimta® is superior (or equivalent) to paclitaxel. There are no peer-reviewed, double-blind studies that provide evidence of superiority (or even comparability) of Alimta® to paclitaxel.

142. The financial impact to Government Programs from the substitution of Alimta® for paclitaxel has been significant, as Alimta® is approximately sixteen times more expensive than paclitaxel. (According to internal Lilly documents, the approximate cost per cycle of Alimta is $4,556.34, compared to approximately $280 for generic paclitaxel.) Lilly has seized on this pricing differential and encouraged physicians to prescribe Alimta® in lieu of generic alternatives on the basis that, under the Average Selling Price reimbursement structure imposed by the MMA, Alimta® will deliver greater profits to the physician than would the generic alternative. When the physicians' reimbursement claims are paid by the Government Programs, the Government Programs have paid more than they otherwise would have had Lilly not encouraged the physician to prescribe the more expensive branded drugs off-label.

1. Lilly Uses Medical References to Drive Off-Label Usage of Alimta®

143. Lilly is acutely aware of several medical studies that discuss various off-label uses of Alimta®, including in combination with carboplatin (in lieu of paclitaxel plus carboplatin). Some of these studies are the same studies that the Compendia have cited in support of the off-label combination. These studies are of dubious reliability and scientific value in determining the relative efficacy and toxicity of an Alimta®/carboplatin combination therapy.

144. For example, the 2005 Zinner study on which the Clinical Pharmacology Compendium citation supposedly supporting an Alimta®/carboplatin combination therapy involved only fifty patients, and its conclusions relate only to tolerability of the combination, not efficacy, and certainly not efficacy relative to the FDA-approved paclitaxel/carboplatin combination. *See* Zinner, RG et al., Phase II study of pemetrexed in combination with carboplatin in the first-line treatment of advanced nonsmall cell lung cancer, *available at*, http://www.ncbi.nlm.nih.gov/pubmed/16258975.

145. Nevertheless, Lilly directed its sales representatives to aggressively use these studies to promote the unapproved, off-label use of Alimta® in combination with carboplatin. Lilly does this by creating laminated Medical References that purport to provide key information regarding these studies in bulleted or tabular (*i.e.*, incomplete) format for sales representatives to use when calling on healthcare professionals. Lilly has required its oncology sales representatives to include these Medical References in their "bags" and to aggressively promote them to physicians, without physician prompting, in order to drive off-label usage of Alimta®. As discussed more fully above, the sales representatives understand that if they do *not* use the Medical References to self-initiate off-label discussions, their jobs will be in jeopardy. *See* discussion *supra*.

146. That Lilly has directed the use of these Medical References to support the off-label promotion of Alimta® is confirmed by the fact that when sales representatives complete "Oncology Medical Information Request" forms (which purport to convey a physician's request to receive off-label information from Lilly's Medical Affairs department), they are required to identify the "SPECIFIC MEDICAL REFERENCE UTILIZED." (Relator Turano has provided

several such forms to the Government, each indicating the use of a Medical Reference to support off-label promotion of Alimta® to a particular physician on a particular date.)

147. As recently as May 2010, Lilly provided updated versions of at least five such "Medical References" to Relator Turano and others that they were instructed to use *sua sponte* in their promotion of off-label uses of Alimta®. Those particular Medical References are:

- Alimta in Elderly Patients;
- Phase III Studies of Alimta plus Gemzar in NSCLC;
- Alimta in Combination with Radiation; and
- Phase 2 Study of Alimta in Combination with [Avastin]

148. Of particular relevance to this Complaint, Lilly also provided each of its sales representatives with a Medical Reference that was entitled: "*What data are available for the use of Alimta® (pemetrexed) in combination with platinum agents for the treatment of non-small cell lung cancer (NSCLC)?*" This Medical Reference included two glossy pages dedicated to a discussion of "Alimta in Combination with Carboplatin or Oxaliplatin," and was designed (and specifically intended) to favorably compare the off-label Alimta®/carboplatin combination to the on-label Alimta®/cisplatin combination.

149. In fact, sales representatives have been instructed to promote this Medical Reference *sua sponte* as a basis upon which physicians should prescribe the Alimta®/carboplatin plus Avastin® combination off-label. Similarly, sales representatives have been instructed to specifically discuss the so-called "Patel Study" that is cited in that Medical Reference, even though it was open-label and involved only 50 patients. *See* Patel, J.D. *et al.*, Phase II Study of Pemetrexed and Carboplatin Plus Bevacizumab With Maintenance Pemetrexed and

Bevacizumab As First-Line Therapy for Nonsquamous Non-Small-Cell Lung Cancer; J. CLIN. ONCOL. 27:1-7 (2009).

150. Importantly, the Patel Study itself acknowledged that it did not provide a direct comparison against the acknowledged standard of care (*i.e.*, paclitaxel/carboplatin/Avastin®). Nevertheless, Lilly directed its sales representatives to promote the Patel Study as evidence that an Alimta®/carboplatin/Avastin® combination was superior to the standard of care, and they did so. (It is worth noting that Dr. Patel and another author of the Patel Study received both consultant and research funding from Lilly.)

151. As indicated, Lilly reinforced the requirement that sales representatives use the Medical References *sua sponte* to promote Alimta® off-label during "Practice Selling" sessions at National Sales Meetings. For example, at the 2006 Lilly Oncology National Sales Meeting at the Westin Park Central hotel in Dallas (February 27 to March 3), Lilly convened multiple "Practice Selling" sessions during which sales representatives were instructed on how to use Medical References to steer physicians toward prescribing unapproved uses and combinations of Alimta® (and Gemzar®). On the final day, each sales representative participated in a simulation in which they were required to "sell" Alimta® (and Gemzar®) to upper management employees (*e.g.*, Product Manager Byron Litton, Regional Sales Director Jim O'Conner and District Sales Manager Michael Polkowitz) who would play the role of the physician. Lilly convened similar "Practice Selling" sessions at the 2007 Lilly Oncology National Sales Meeting (February 26 – March 2) in San Antonio, Texas. Due to the participation of high-level supervisors in these exercises, Relator Turano understood that he was *required* to use the Medical References to prompt off-label promotions and prescriptions, and that his job would be in jeopardy if he failed to do so.

152. District Manager Michael Polkowitz, Relator Turano's immediate supervisor, has led role-play training exercises at several District meetings, including at the Crown Plaza AMA Conference Center (January 24, 2007 and June 14, 2007) and at the Newark Marriott (October 24-26, 2007). During these training exercises, Polkowitz specifically instructed Relator Turano and others that they should be using Medical References to provoke off-label sales discussions with physicians. Relator Turano understood that he had no choice in the matter if he wanted to keep his job.

153. DM Polkowitz routinely reinforces this instruction during supervisory ride-alongs with Relator Turano. For example, during one ride-along sales call to Dr. Bruce Kappel of Medical Oncology Associates in Woodbury, New York on August 12, 2008, DM Polkowitz deliberately steered the conversation directly to an off-label topic. Specifically, Dr. Kappel had just returned from a medical symposium on advances in the treatment of NSCLC. DM Polkowitz, being fully aware that such symposia typically present Taxol® (a/k/a paclitaxel)/carboplatin/Avastin® as the standard of care for NSCLC, told Dr. Kappel *sua sponte* about data from the off-label Patel Study. When Dr. Kappel asked DM Polkowitz if he was suggesting that Dr. Kappel should treat his patients with Alimta®/carboplatin/Avastin® instead, Polkowitz responded "[a]bsolutely – just swap the Alimta® for the Taxol®." Dr. Kappel said he would do so. His utilization of Alimta® increased substantially after the sales call. DM Polkowitz later described the visit as a "huge success." Importantly for purposes of this Complaint, a very high percentage of Dr. Kappel's patients are Medicare beneficiaries.

154. Not all physicians are enamored of DM Polkowtiz's aggressive, off-label tactics. Thus, for example, two prominent oncology practices – North Shore Hematology Oncology Associates and Huntington Medical Group – initially prohibited any further interaction between

DM Polkowitz and their physicians and staff for about a year, but ultimately extended that ban to all Lilly sales representatives.

155. But, the pressure to increase Alimta® sales to replace lost revenue in other product lines was growing. During the 2009 Lilly Oncology National Sales Meeting at the Arizona Biltmore in Phoenix, Lilly again convened multiple "Practice Selling" sessions during which sales representatives were instructed on how to use Medical References to steer physicians toward prescribing unapproved uses and combinations of Alimta® and Gemzar®. Among the questions that sales representatives were *directed* to pose to physicians were:

- "Doctor, I'm asking you to use Alimta® first-line. You can decide on what platinum to use."
- "Doctor, based on evidence based medicine, do you really think using taxol/carbo/Avastin® is the absolute best choice for treating an adeno NSCLC patient? Why not swap the taxol out and use Alimta® instead? This Medical Reference demonstrates that Alimta® can be used with other agents."
- "Doctor, Avastin needs to be used with chemo, so why not use Alimta® as your backbone therapy with Avastin®?"

Clearly, Lilly had instructed its sales representatives to promote the drug off-label.

156. The combined effect of the initial training by Lee Thomas, the practice selling sessions at National and District meetings, the ride-along demonstrations by District Manager Polkowitz, and the specific instructions from DM Polkowitz, sent a clear and unmistakable message to Relator Turano and other sales representatives: they were to use the Medical References to initiate off-label promotions, or they would lose their jobs.

157. The sales representatives followed their instructions, with great success. Their use of the Medical References to self-initiate off-label promotion of the Alimta®/paclitaxel

combination led to increased Alimta® utilization by physicians at the following medical practices and institutions, among others:

- Memorial Sloan Kettering Cancer Center in New York City, including satellite clinics in Commack, New York and Rockville Centre, New York;
- North Shore University Hospital in Manhasset, New York, including the Monter Cancer Center in Lake Success, New York;
- Winthrop Oncology Group/Winthrop Hospital in Minneola, New York;
- Hematology Oncology Associates of Western Suffolk in Bay Shore, New York;
- Medical Oncology Associates in Woodbury, New York;
- Huntington Medical Group in Huntington, New York; and
- Tomao, Marino, McNelis, Ginsburg & Chandok Oncology Group in Port Washington, New York.

158. On May 18, 2010, perhaps in an effort to eliminate the paper trail of its wrongdoing, Lilly changed its policy regarding the use of Medical References and instructed Sales Directors, District Sales Managers, Sales Specialists and the Internal Oncology Brand Team to destroy all Medical References in their possession. The destruction order came in the form of a written "Oncology Field Communication" from Oncology Planner Holly Seymour.

159. Lilly had earlier issued a similar, though not as far-reaching, "ALIMTA, GEMZAR & Lilly Oncology Material Destruction Notice" dated December 11, 2009, assertedly issued "[i]n response to regulatory guidance," instructing Relator Turano and others to "destroy all remaining stock" of eighteen different "promotional items" including:

- an "NSCLC Staging Guide";
- an "Alimta 1st Line NSCLC" Leave Behind;

- an "Alimta Dosing Administration and Guidelines" document;
- an "Alimta 1st Line NSCLC Slim Jim";
- an "Alimta Payer Value Message" document; and
- an "NSCLC Participant Guide."

Recipients of this Destruction Notice were required to destroy the covered materials "[b]y the end of day on December 24" and to document their compliance by signing an electronic signature through an "on-line exam."

160. In fact, Lilly made a routine practice of instructing its sales representatives to destroy promotional materials and aids.

2. Lilly Uses Paid "Thought Leaders" to Promote Alimta® Off-Label

161. Lilly understands that using influential lung cancer researchers to promote Alimta® for off-label uses can be a very effective way to grow market share. Lilly intends that these scientists will speak not about on-label uses of Alimta® (for which further promotion is not really necessary), but rather about off-label uses of which practicing physicians may not be aware. Thus, Lilly routinely pays such doctors to give such promotional talks to other healthcare professionals precisely *because* they can be relied upon to initiate off-label discussions with members of the audience.

162. Confirming the promotional nature of these talks, Lilly specifically instructs its sales representatives to arrange speaker programs for their large or under-performing accounts. Moreover, Lilly actively encourages its sales specialists to employ speakers based on the extent to which they are "on board" with Lilly's message, as sales representative Lindsay Bloom (a District "Program Champ" for speaker programs), recently made clear to New York area sales

specialists when she provided a list of thirteen "***highly*** recommended" (emphasis in original) speakers on February 9, 2010.

163. As discussed above, Relator Turano and others understood that they were *not* supposed to interrupt the off-label promotional message or report or criticize the speaker for going off-label, since that would undercut the underlying sales pitch. They understood that the company's expectation was that they were to remain silent in the face of off-label promotion – or risk losing their jobs – because, when sales supervisors such as DM Polkowitz attended the presentations and observe off-label promotions, they remained silent themselves.

164. Among the speakers that Lilly has paid to lead off-label promotional talks for Alimta® are:

(a) **Dr. Chandra Belani**

165. Chandra Belani (Penn State Hershey Medical Center, Hershey, PA) is one of Lilly's most highly and frequently paid promotional speakers. In addition, Dr. Belani has conducted and presented Lilly-sponsored research, including research into off-label maintenance use of Alimta® that was presented at the 2009 ASCO Annual Meeting in Orlando May 29 – June 2, 2009. Relator Turano attended at least one promotional talk by Dr. Belani that was sponsored by Lilly and arranged by another sales representative. During the program, Dr. Belani initiated an off-label discussion of the use of Alimta®/carboplatin/Avastin®.

166. In 2009, Lilly paid Dr. Belani almost $60,000 for "Healthcare Professional Education Programs" and "Advising/Consulting & International Education Programs." During the first quarter of 2010 alone, Lilly paid Dr. Belani more than $30,000 for the same services.

(b) **Dr. Harry Harper**

167. Lilly paid Dr. Harry Harper (Hackensack University Medical Center, Hackensack, NJ) $1,700.00 to deliver a promotional talk entitled: "*Use of Histology to Select Cytotoxic Therapy for the Treatment of Advanced Nonsquamous NSCLC*" on or about July 14, 2010 at Morton's Steakhouse in Great Neck, New York. Relator Turano, his sales partner, and the sales representative responsible for Hackensack University Medical Center also were present at this event, which was open to all local oncologists and their staffs. Attendees included Dr. Barbara Seligman and Dr. Ida Ashley Geeraerts, both of Queens Hospital Center in Jamaica, New York. Immediately after presenting the Lilly-approved slide deck, Dr. Harper initiated *sua sponte* a conversation in which he promoted the off-label Alimta®/carboplatin/Avastin® combination, including a discussion of how he uses it in his practice. Relator Turano and his Lilly sales colleagues did not interrupt the discussion, nor criticize or report Dr. Harper, because their supervisors had made clear to them that the speakers were *supposed* to speak off-label, and that the sales representatives were not supposed to interfere with the sales pitch.

(c) **Dr. Ronald B. Natale**

168. Dr. Ronald B. Natale (Cedars-Sinai Medical Center, Los Angeles, CA) is one of Lilly's most prominent and highly paid promotional speakers, and Lilly has paid him to speak at multiple venues within the New York City District. Relator Turano attended two such promotional programs during the 2007/2008 time frame, both at New York area restaurants, during which Dr. Natale self-initiated an off-label promotion of Alimta®/carboplatin/Avastin®. Based on the example and implicit instruction conveyed by his supervisor, DM Polkowitz, Relator Turano did not interrupt the presentation, nor criticize or report Dr. Natalae, because it was clear that the consequence of doing so would be that he would lose his job with Lilly.

169. During the first quarter of 2010, Lilly paid Dr. Natale $5,750 for "Advising/Consulting & International Education Programs" plus an additional $1,514 in travel related expenses. Inexplicably, however, historic data relating to Dr. Natale's paid promotional activities for Lilly have been removed from the Lilly Lecture Bureau database.

(d) **Dr. Roman Perez-Soler**

170. Lilly has paid Dr. Roman Perez-Soler to deliver an off-label message on multiple occasions. For example, he was paid to deliver a presentation on the off-label use of Alimta® at the H2O Seafood Grill in Smithtown, New York on July 11, 2006 for the staff at North Shore Hematology Oncology Associates and the staff oncology nurses at St. Catherine of Siena Medical Center. Lilly's B2B Associate Rob Rubin and District Manager Michael Polkowitz also attended this event in order to explain to attendees, who were members of the ION group purchasing organization, that there were significant financial incentives for them to prescribe greater quantities of Alimta®. Neither Rubin nor Polkowitz took any action to stop the off-label promotion nor criticize or report Dr. Perez-Soler for initiating an off-label discussion, nor did either of them instruct Relator Turano that he should do so. This confirmed Relator Turano's understanding of Lilly's expectations.

171. Lilly paid Dr. Perez-Soler to deliver similar presentations at Villa Paul restaurant in Hampton Bays, New York on May 15, 2007 for the staff of Eastern Long Island Hematology Oncology in Riverhead, New York, and at Blackstone Restaurant in Farmingdale, New York on June 19, 2007 for any oncologist in the Long Island area. Dr. Brian McNelis is one particularly busy oncologist (from Port Washington, New York) who attended the event at Blackstone.

172. At each of these programs, Dr. Perez-Soler's self-initiated off-label discussion included promotion of the Alimta®/carboplatin combination, and Lilly expected this would occur

since that combination has been a focus of Dr. Perez-Soler's research. In fact, one of the reasons that Lilly prefers to employ Dr. Perez-Soler is that he can be relied upon to initiate and promote a favorable, off-label message for Alimta® in combination with carboplatin.

173. According to Lilly's online Faculty Registry, Dr. Perez-Soler conducted 30 speaker programs for Lilly in 2009 alone, and was paid $68,568.70 by Lilly for his speaking activities. Lilly has paid Dr. Perez-Soler an additional $12,158.00 for his speaking activities in the first quarter of 2010.

174. In addition to the foregoing, Dr. Perez-Soler has served as a paid panelist at various CME programs sponsored by Lilly, including the Fifth Annual New York Lung Cancer Symposium in 2009, and he is scheduled to be a paid panelist at the 2010 event as well.

(e) **Dr. Harry Raftopoulos**

175. Lilly paid Dr. Raftopoulos to deliver a promotional program on July 22, 2009 on the off-label use of Alimta® in combination with Avastin®. The program was held at Morton's Steakhouse in Great Neck, New York, and attendees included Dr. Debra Ferman of North Shore Hematology Oncology Associates, as well as other physicians and oncology fellows, including Syed Ali, Kit Cheng, Mary Leong, Guareet Multani, Hina Nauqi, and Sadia Riaz. Relator Turano and Janice Conte also attended on behalf of Lilly. Neither of them interrupted the off-label promotion, nor criticized or reported Dr. Raftopoulos for initiating an off-label discussion. Relator Turano knew that if he did so he would place his own job in jeopardy.

176. Lilly paid Dr. Raftopoulos to deliver a promotional program on September 27, 2007 on the off-label use of Alimta® in combination with Avastin®. The program was held at Carltun on the Park in East Meadow, New York, and it was open to all oncology fellows at North Shore University Hospital. Relator Turano attended this event, but he did not interrupt the off-

label promotion, nor criticize or report Dr. Raftopoulos for initiating an off-label discussion, because it was clear that doing so would place his own job in jeopardy.

177. According to Lilly's online Faculty Registry, Dr. Raftopoulos conducted thirteen speaker programs for Lilly in 2009 alone, and was paid $18,175.00 by Lilly for his speaking activities. Dr. Raftopoulos also is scheduled to be a paid panelist at the Sixth Annual New York Lung Cancer Symposium, sponsored by Lilly.

(f) **Anne Marie Shaftic**

178. Lilly paid Nurse Practitioner Anne Marie Shaftic $1,000.00 to deliver a talk entitled: "*Use of Histology to Select Cytotoxic Therapy for the Treatment of Advanced Nonsquamous NSCLC*" on or about July 27, 2010 at Long Island Jewish Hospital. During the talk, Nurse Practitioner Shaftic initiated a promotional discussion of the Alimta®/carboplatin combination from a nursing and management perspective. This event was organized by Relator Turano's former sales partner, John Giouvalakis, and Shaftic delivered similar presentations at Queens Long Island Medical Group in Valley Stream, New York and Wycoff Heights Medical Center in Brooklyn, New York, both on August 17, 2010. Relator Turano attended the event at Long Island Jewish Hospital, and did not interrupt the off-label promotion, nor criticize or report NP Shaftic for initiating an off-label discussion, because it was clear that doing so would place his own job in jeopardy.

(g) **Dr. Mark A. Socinski**

179. Dr. Mark A. Socinski (UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC), is a highly paid Lilly speaker, and a paid investigator on several Lilly-funded research trials. Lilly has paid Dr. Socinski to promote the off-label use of Alimta® to multiple physician practices. For example, on or about June 28, 2006, Lilly paid Dr. Socinski to lead a presentation

for Drs. Philip Schulman and John Fiore of the Memorial Sloan Kettering Cancer Center facility in Commack, New York, in which he initiated discussion regarding off-label uses of Alimta® to treat thoracic cancer, as well as the Alimta®/carboplatin combination in particular. Lilly expected this would occur, since that combination has been a focus of Dr. Socinski's research. Relator Turano attended this event, and did not interrupt the off-label promotion, nor criticize or report Dr. Socinski for initiating an off-label discussion, because he knew that doing so would place his own job in jeopardy.

180. In fact, one of the reasons that Lilly prefers to employ Dr. Socinski is that he can be relied upon to initiate and promote a favorable, off-label message for Alimta® in combination with carboplatin. According to Lilly's online Faculty Registry, Dr. Socinski conducted 27 speaker programs for Lilly in 2009 alone, and was paid more than $72,450.00 by Lilly for his speaking activities.

(h) **Dr. Joseph Treat**

181. Lilly paid Dr. Joseph Treat to deliver an off-label research presentation, in conjunction with a sales promotion by Relator Turano and sales representative Janice Conte, on February 12, 2007 to the office of Dr. Michael Buchholtz in Huntington, New York. Formerly a full-time private research physician, Dr. Treat had, at the time of this presentation, recently become a part-time Lilly *employee*, while still maintaining his private activities on a part-time basis. This presentation and format was initiated and encouraged by District Manager Polkowitz, with the knowledge and approval of Lilly Oncology management in Indianapolis. As Lilly intended, Dr. Treat initiated an off-label discussion regarding the use of an Alimta®/carboplatin combination therapy.

3. The FDA Has Criticized Lilly for its Improper Promotion of Alimta®

182. Not surprisingly, Lilly has been the recent recipient of a DDMAC Warning Letter from the FDA. On July 27, 2006, DDMAC informed Lilly that an Alimta® patient brochure distributed by Lilly was misleading because it omitted material facts and risk information essential to the safe and effective use of Alimta®. At the time, Alimta® was approved for only two indications: (i) in combination with cisplatin, for the treatment of patients with malignant pleural mesothelioma whose disease was unresectable or who were otherwise not candidates for curative surgery; and (ii) as a single-agent for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. The FDA-approved label also made clear that the effectiveness of Alimta® in second-line NSCLC was based on a surrogate endpoint because there were no controlled trials demonstrating clinical benefit, such as a favorable survival effect or improvement of disease-related symptoms. The FDA-approved label also made clear that the use of Alimta® was associated with a number of risks, including risk of fetal harm.

183. DDMAC observed, however, that Lilly's patient brochure for Alimta® "omit[ted] material facts" because it failed to identify either of the approved indications and because it failed to disclose that approval of the NSCLC indication was based on a surrogate endpoint, because there were no controlled trials demonstrating clinical benefit. DDMAC put these failures in their appropriate context, concluding:

> The failure to specifically state either approved indication [was] exacerbated not only by vague reference to unspecified cancers, but also by the fact that the brochure provides information and references for a number of other types of cancers for which Alimta is not indicated, potentially creating the misleading impression that Alimta is approved to treat a wide range of cancers. This is particularly concerning because, for some of these cancers, there exist therapies that have proven to confer clinical benefit.

184. DDMAC also concluded that Lilly's failure to include Alimta®'s indication(s), and the limitation on the NSCLC indication in the brochure was exacerbated by other statements in the brochure that created a "misleading impression that treatment with Alimta has been proven to confer clinical benefits in the treatment of unspecified cancers."

185. Finally, DDMAC concluded that the patient brochure was "misleading because it fail[ed] to reveal that Alimta may cause fetal harm when administered to a pregnant woman and that pregnant women should be so advised, and that patients considering pregnancy should be advised to avoid becoming pregnant while taking Alimta."

186. Plainly, as DDMAC observed, Lilly has endeavored to promote Alimta® off-label for the treatment of a wide variety of cancers, and to suppress important safety information, since at least 2006. What is particularly galling is that, even after it received the DDMAC warning letter, Lilly did not end its fraudulent schemes, but instead accelerated them.

VIII. LILLY CORRUPTED THE COMPENDIA PROCESS

187. As originally conceived, the Compendia were intended to speed the pace by which medically-accepted anti-cancer drugs would reach the patients who need them. However, pharmaceutical companies, including Lilly, have corrupted the process by which the Compendia determine what uses for drugs like Gemzar® and Alimta® will be considered "medically-accepted" and thus reimbursable. As a result, although "[o]ncologists rely on Compendia for up-to-date access to evidence and reimbursement information for off-label indications . . . [c]urrent Compendia lack transparency, cite little current evidence, and lack systematic methods to review or update evidence." *See* Abernethy, A.P., *et al.*, Systematic Review: Reliability of Compendia Methods for Off-Label Oncology Indications, 150 ANN. INTERNAL MED. 336-343 (2009) (the "Abernethy Study").

188. The Abernethy Study made several alarming findings, including the following conclusion upon the authors' review of fourteen off-label indications for cancer drugs that were cited in the Compendia:

> Cited evidence was scanty and inconsistent across Compendia, which raises questions about the processes by which evidence is identified and selected to generate recommendations, the potential biases or conflicts of interest that affect decisions of whether to include an indication or how to present the evidence, and the comprehensiveness and quality of the evidence that the Compendia include. . . . The evidence included in the Compendia we evaluated did not seem to be updated in a timely, regular, and explicit manner.

See Abernethy Study, *supra*, at 341. The authors also concluded:

> In addition to the limited number of research studies cited, the citations were often neither the most recent nor derived from the highest available level of evidence. All Compendia lacked explicit, systematic procedures for determining inclusion of off-label indications, and stated conditions for including non-FDA indications did not match actual practices of inclusion.

Id.

189. Pharmaceutical companies have contributed to the problems with the Compendia by, among other things, funding marginal studies and then foisting those studies onto the Compendia publishers. They do this because the "[p]harmaceutical manufacturers have a direct interest in maximizing the number of accepted indications that are listed in approved Compendia, and thus eligible for payment. Given this basic motivation, industry could be expected to favor policies that accept marginal data on a drug's effectiveness as evidence justifying reimbursement for that agent." *See* McKinney *et al.*, WHITE PAPER: POTENTIAL CONFLICT OF INTEREST IN THE PRODUCTION OF DRUG COMPENDIA (Apr. 27, 2009), *available at*, http://www.cms.gov/determinationprocess/downloads/id64TA.pdf.

190. Given the not insignificant conflicts of interest among the Compendia publishers and the pharmaceutical companies, whether a particular use is "supported by" a Compendium

citation may depend on a variety of factors, including the type of drug and indication at issue, the Compendium's assessment of the drug's efficacy in treating the indication, and, critically, the content of the Compendium citation and the scope and outcome of the studies described therein. Thus, the Compendium citation itself must not be taken at face value, but must be examined for indicia of scientific reliability and trustworthiness.

191. Lilly has corrupted the Compendium process in two ways: first, by currying improper favor with the Compendia and key panelists through financial incentives paid to them and the Compendia publishers; and second, by sponsoring and then promoting obviously deficient studies as "support" for non-FDA-approved indications.

A. LILLY HAS CORRUPTED THE NCCN COMPENDIUM PROCESS THROUGH FINANCIAL PAYMENTS TO THE NCCN AND ITS PANELISTS

192. Relationships with the drug industry and conflicts of interest in the development of the Compendia exist at both the individual panelist level (*i.e.*, panel participants may have industry ties) and the institutional level (*i.e.*, the sponsoring group may rely on industry funding for guidelines). These relationships raise the possibility of conflicts of interest and undue influence at each step in the Compendia development process.

193. Supposed "consensus groups" like NCCN require industry funding to develop their Compendium and practice guidelines ("Guidelines"). Thus, they propose topics that will attract industry funding (*e.g.*, a guideline on *how* to use a product, but not *whether* it should be used). Among the topics proposed to potential funders, drug companies favor topics and questions for which the evidence is most likely to support conclusions favorable to their particular drug products. The lack of transparency in the development of the Guidelines "limits the ability of guideline readers to consider financial relationships and conflicts of interest as part

of their assessment of the credibility of a set of guidelines." *See* The National Academies: Institute of Medicine: Conflict of Interest in Medical Research, Education, and Practice, at 205 (April 21, 2009) (Full Text Available at www.nap.edu).

194. Over the past decade, the NCCN Guidelines and the associated NCCN Compendium have become the "standard" in determining the standard of care in oncology in the United States. However, to date, and most controversial, there has been little transparency in how the NCCN panels determine what drug regimens to recommend. Not only is there a lack of disclosure of what (and how) drug companies submit information for inclusion in the NCCN Guidelines and Compendium, there has been no disclosure of the panel deliberations. There are no published requirements for the minimum level of evidence required for NCCN approval, no disclosure of what "evidence" the NCCN panels have relied on for their determinations, no public information regarding the actual deliberations over the submissions, nor any information about which expert panelists participated, which recused themselves, nor what the final votes were for each approval.

195. Most troubling is that the NCCN, its Guidelines, Compendium and its panelists remain laced with numerous conflicts of interest due to their substantial financial ties to the drug industry in general, and to Eli Lilly in particular here.

196. NCCN itself is closely intertwined with Eli Lilly. For example, according to the Eli Lilly website (which discloses grants to outside entities), Lilly made ongoing grants of *at least* $1.9 million to NCCN from 2008 through the first quarter of 2010. Those grants provided funding for:

Q1 2008

- 13th Annual Conference: Clinical Practice Guidelines and Quality Cancer Care in Q1 2008 ($78,807.00)
- Breakfast Symposium: Treating Lung Cancer in Women ($125,000.00)
- 2008 Non-Small Cell Lung Cancer Guidelines Regional Symposia Series ($100,000.00)
- Enduring Materials of "Update: Lung Cancer Guidelines" ($53,250.00)

Q2 2008

- National Comprehensive Cancer Network, Inc NCCN Non-Small Cell Lung Cancer Medscape Spotlight Program ($25,000.00)

Q3 2008

- NCCN Non-Small Cell Lung Cancer Medscape Spotlight Program ($25,000.00)

Q4 2008

- Non-Small Cell Lung Cancer Guidelines Regional Symposia Series ($100,000.00)
- 14th Annual Conference: Clinical Practice Guidelines and Quality Cancer Care ($200,000.00)
- 2009 Non-Small Cell Lung Cancer Guidelines Regional Symposia Series ($75,000.00)
- 2008 Breast Cancer Guidelines Regional Symposia Series ($50,000.00)
- Enduring Materials of "Update: Lung Cancer Guidelines" ($53,250.00)
- Use of EGFR in the Treatment of Pancreatic Cancer Held in Conjunction with the NCCN 14th Annual Conference ($50,000.00)

- Symposium: New Advances in the First Line Treatment of Non-Small Cell Lung Cancer Held in Conjunction with the NCCN 14th Annual Conference ($164,325.00)

Q1 2009

- 2nd Annual NCCN Asian Scientific Congress and the Development of Asian Scientific Statements/Local Editions for the NCCN Clinical Practice Guidelines in Oncology Educational Program ($25,000.00)

Q2 2009

- NCCN Discovery Health Channel Medical Education Program "Issues in Advanced Non-Small Cell Lung Cancer" Educational Program ($200,000.00)
- National Comprehensive Cancer Network, Inc. Support of NCCN Oncology Comparative Effectiveness Work Group and Policy Summit Advocacy ($50,000.00)

Q4 2009

- 15th Annual Conference: Clinical Practice Guidelines and Quality Cancer Care™, Educational Program ($200,000.00)
- Symposium: Maintenance Therapy in Non-Small Cell Lung Cancer Held in Conjunction with the NCCN 15th Annual Conference, Educational Program ($158,790.00)
- National Hispanic Caucus of State Legislators NHCSL Seventh National Summit of Hispanic State Legislators, Charitable Contribution ($15,000.00)

Q1 2010

- Enduring Materials of "Maintenance Therapy in Non-Small Cell Lung Cancer" Presented at the NCCN 15th Annual Conference Educational Program ($209,920.00)
- Request for Support and Participation in NCCN Risk Evaluation and Mitigation Strategies (REMS) Work Group and Policy Summit Advocacy ($25,000.00)

197. In addition, Eli Lilly is listed as a corporate member of NCCN, and as such apparently contributed an undisclosed additional sum of money to NCCN. NCCN also offers corporate contributors the opportunity to support numerous of its specific activities, including sponsoring the NCCN Compendium itself. Since NCCN does not disclose who the corporate contributors are for the Compendium or the Guidelines, however, it is unclear whether Eli Lilly is a sponsor.

198. Beyond the direct monies Eli Lilly provides to NCCN, Eli Lilly provides significant monies directly to specific NCCN panelists. For example, the NCCN Compendium has a Non-Small Cell Lung Cancer Panel that, as its name suggests, plays a significant role in determining which off-label indications will be deemed to have sufficient evidentiary support to warrant a citation that would justify Government Program reimbursement. Of the thirty-six current members of that panel, seven (roughly twenty percent) have acknowledged serving as a speaker, consultant, expert witness or advisory board member for Lilly. One such individual is Jyoti Patel, who is principal author of the study, discussed *supra*, that Lilly sales representatives actively promote in order to encourage physicians to prescribe the off-label Alimta®/carboplatin/Avastin® combination.

199. NCCN recognizes the very real concerns with its independence arising from the large sums of money that panelists receive from drug makers like Eli Lilly. According to its own Conflict of Interest Policy:

> While corporate and industry involvement plays a growing role in the support of oncology research, the financial incentives that accompany such involvement may lead to conflicts of interest. NCCN also recognizes that the majority of NCCN Guidelines Panel Members have complex relationships with industry including conducting research in areas such as medical devices, diagnostics, drugs, and biologics. . . . [F]inancial conflicts of interest have the potential to introduce biases into the development process of NCCN Guidelines and NCCN Task Forces, thereby potentially affecting the integrity of the NCCN Guidelines or NCCN Task Forces.

200. As a result of their dealings with Lilly, NCCN – including its Guidelines, Compendium and many of its panelists – remain inherently conflicted.

201. Here, this conflict resulted in, for example, unreliable Compendium support for Alimta®, *see* discussion *supra*, and unreliable clinical practice Guidelines for both Gemzar® and Alimta®, which together were intended to create extensive off-label use of Lilly's drugs under treatment algorithms (*i.e.*, essentially step-by-step treatment decision trees) developed by NCCN. For example, the NCCN Guidelines mandate the use of Gemzar® as first-line therapy for breast cancer and metastatic head and neck cancer, and as second-line therapy for bladder and cervical cancer, and they mandate the use of Alimta® plus carboplatin as first-line therapy for NSCLC, and as second-line therapy for bladder and cervical cancer, even though *none* of these uses have been approved by the FDA. Not coincidentally, the NCCN Compendium supports the off-label use of Gemzar® in nineteen different treatment contexts (including the foregoing), and it supports the off-label use of Alimta® in six different treatment contexts (including the foregoing).

202. While the NCCN Guidelines/Compendium do not spell out how much Eli Lilly contributed financially, nor its role in their drafting, it is clear the NCCN

Guidelines/Compendium were the product of the inherently biased (and therefore suspect) review process.

B. LILLY HAS CORRUPTED THE COMPENDIA PROCESS BY SPONSORING AND PROMOTING MARGINAL CLINICAL RESEARCH

203. Leveraging the influence it has acquired through financial support of the Compendia publishers and their decision-makers (in particular, NCCN), Lilly has promoted their citation to unreliable clinical studies in order to render non-FDA-approved uses of Gemzar® and Alimta® nominally reimbursable.

204. For example, the article cited by Clinical Pharmacology as allegedly providing support for a Gemzar®/docetaxel combination to treat breast cancer is merely a summary of four small Phase II studies, three of which included fewer than forty evaluable patients, and all of which were, apparently, open-label with no placebo control. *See* Silvestris, N. *et al.*, Rationale for the use of gemcitabine in breast cancer (review), 24 INT'L. J. ONCOL. 389-398 (2004) (citing Mavroudis, D. *et al.*, Salvage chemotherapy in anthracycline-pretreated patients with docetaxel and gemcitabine: a multicenter phase II trial, 10 ANN. ONCOL. 211-215 (1999); Fountzilas, G. *et al.*, Docetaxel and gemcitabine in anthracycline-resistent advanced breast cancer: a Hellenic Cooperative Oncology Group phase II study, 18 CANCER INVEST. 503-509 (2000); Laufman, LR *et al.*, Monthly docetaxel and weekly gemcitabine in metastatic breast cancer: a phase II trial, 12 ANN. ONCOL. 1259-1264 (2001); Pellegri, A. *et al.*, Gemcitabine and docetaxel given every 2 weeks as first-line therapy for metastatic breast cancer (MBC): results of a GEICAM phase II study, Proc. AM. SOC. CLIN. ONCOL. 21: 2002 (abstr. 1950)).

205. The four articles cited by Silvestris provide little (if any) support for the Gemzar®/docetaxel combination cited in Clinical Pharmacology. For example, the Laufman

study, *supra*, reported severe toxicity and asked "whether the toxicities associated with this doublet are justified in patients with incurable cancer." The Mavroudis study, *supra*, acknowledged its inadequacy, stating: "Whether or not this treatment would also lead to prolongation of survival can only be answered by prospective randomized studies." The Fountzilas study, *supra*, reported only that the Gemzar®/docetaxel combination was "moderately active" in anthracycline-resistant advanced breast cancer, and it acknowledged the need for further studies. And the fourth study cited by Silvestris – the Pelegri study – does not appear to have ever been published other than as an abstract, lending serious doubt to the credibility of its conclusion that the Gemzar®/docetaxel combination is "highly active." In sum, the Silvestris article that the Clinical Pharmacology Compendium considered to be so persuasive is little more than a bibliography of marginal studies that are demonstrably inadequate to support FDA approval.

206. Similarly, the 2005 Zinner study on which Clinical Pharmacology based its citation for an Alimta®/carboplatin combination involved only fifty patients, and its conclusions related only to tolerability of the combination, not efficacy – and certainly not efficacy relative to the FDA-approved paclitaxel/carboplatin combination. *See* Zinner *et al.*, Phase II study of pemetrexed in combination with carboplatin in the first-line treatment of advanced nonsmall cell lung cancer, 104 CANCER 2449-56 (2005). Indeed, the study authors only concluded that further trials were "warranted."

207. The two citations in the NCCN Compendium for an Alimta®/carboplatin combination, *supra*, are even less reliable since NCCN inexplicably refuses to identify the studies upon which the citations are based. The citations are deficient on their face because they

provide *no* indicia of reliability, and thus they should not be considered to support the off-label uses.

208. It appears that the first NCCN citation identified *supra* (*i.e.*, Alimta® in combination with cisplatin or carboplatin as first-line therapy for recurrence or metastasis in patients with performance status (PS) 0-2 or elderly patients) may be based on a study by researchers at the Chinese PLA General Hospital in Beijing. *See* Zhang, G-Z *et al.*, Pemetrexed plus cisplatin/carboplatin in previously treated locally advanced or metastatic non-small cell lung cancer patients, 29 J. EXPERIMENTAL & CLIN. CANCER RES. 38 (2010). If so, there are significant limitations on the reliability of that study including, for example, that it appears to have been an open-label, non placebo-controlled study involving only 53 patients – and only 21 of them received Alimta® plus carboplatin. Further, the median overall survival time was only ten months and the best the study authors could conclude was that "[l]ocally advanced or metastatic NSCLC patients previously treated with platinum-based chemotherapy could benefit from pemetrexed plus cisplatin/carboplatin chemotherapy with tolerable adverse events." *Id.* (emphasis added).

209. It appears that the second NCCN citation identified *supra* (*i.e.*, Alimta® in combination with cisplatin or carboplatin and Avastin® as first-line therapy for recurrence or metastasis in patients with PS 0-1 nonsquamous cell histology and no history of hemoptysis) may be based on a study presented at the 2008 Annual Meeting of the American Society of Clinical Oncology. *See* Patel, J.D., Pemetrexed and carboplatin plus bevacizumab with maintenance pemetrexed and bevacizumab as first-line therapy for advanced non-squamous non-small cell lung cancer (NSCLC), J. CLIN. ONCOL., 26: 2008 (May 20 suppl; abstr. 8044)). This study, too, has significant limitations on its reliability, principal among them being that it appears

to have been an open-label, non-placebo controlled study that enrolled only 51 patients. Even the authors apparently recognized its limited utility, as they concluded only that the combination therapy at issue is "feasible with an acceptable toxicity profile" – hardly a ringing endorsement.

IX. LILLY HAS USED ITS GROUP PURCHASING ORGANIZATION DEALS TO ADVANCE ITS FRAUDULENT MARKETING SCHEME

A. BACKGROUND ON GROUP PURCHASING ORGANIZATIONS

210. As discussed *supra,* Group Purchasing Organizations are buying consortiums or associations of hospitals and healthcare organizations designed to leverage the aggregate purchasing power of members by associating to negotiate contract terms with various suppliers of drugs, medical devices and other goods and services. GPOs do not typically purchase anything from the suppliers, but, once a contract is in place, the member hospitals and healthcare organizations can make purchases under it. *See, e.g.*, Department of Health and Human Services, Office of Inspector General ("OIG") Report: "Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members", (A-05-03-00074) (Jan. 19, 2005). The GPOs then make the covered products directly available to healthcare professionals, including hospitals, clinics and physicians, at a discount.

211. The term "group purchasing organization" is defined at 21 C.F.R. § 203.3 as follows:

> (o) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity

B. LILLY HAS USED ITS GPO DEALS TO BOLSTER ITS FRAUDULENT MARKETING SCHEME

212. In an effort to bolster its fraudulent marketing scheme, Lilly formed alliances with three dominant oncology GPOs to incentivize physicians to prescribe Gemzar® and Alimta® off-label.

213. Three primary GPOs dominate the oncology market through their contracted networks of oncologists: (i) ION, which is owned by AmeriSourceBergen, "controls" some 50% of the oncology market; (ii) US Oncology, which controls 20%; and (iii) Onmark, which is owned by McKesson, controls 30%.

214. Under its oncology GPO contracts, Lilly has established Gemzar® and Alimta® sales objectives for each healthcare provider that is a member of the particular GPO. These objectives are based on historic sales performance, buying patterns and trajectories, and reflect substantial volume growth from period to period. Oncologists that are members of the GPO are eligible for significant cash rebates on their Gemzar® and Alimta® purchases as the volume of those purchases increases and meets specified targets.

215. Lilly closely monitors each oncologist's progress towards these sales goals, and shares that information with sales representatives. Then, either a Lilly Business-to-Business ("B2B") Associate (*e.g.*, Rob Rubin, Alan McWilliams) or a sales representative (*e.g.*, Relator Turano) is directed to follow up with the oncologist to push the prescribing of greater quantities of Gemzar® and/or Alimta® (including for the off-label uses described in this Complaint), in order to be eligible for the next tier of cash rebates. Lilly calls this process "GPO Pull-Through," and has instructed its sales representatives on how to maximize GPO Pull-Through at, for example, the New York City District meeting at the Glen Cove Mansion Hotel and Conference Center in October 2006.

216. In essence, sales representatives are trained and instructed to tell physicians and healthcare providers that they should prescribe Gemzar® and Alimta® off-label, in lieu of less expensive drugs on-label, because doing so will increase the provider's profits. Lilly thus improperly incentivizes physicians, at the expense of Government Programs, to use more Alimta® and Gemzar® than is necessary or appropriate, with the promise of increased profits for physicians (and in turn Lilly and alliance partner GPOs).

217. It merits emphasis that Lilly places significant pressure on its sales representatives to deliver sales results that match the ever-increasing volumetric objectives that are set by the company. Sales representatives are instructed to achieve these objectives "by any means possible" and they are told that the GPO contracts and Government Program reimbursement schemes are tools to be used at their disposal.

218. Here are examples of how oncology GPO deals drove off-label sales of Gemzar® and/or Alimta®:

1. North Shore Hematology Oncology Associates

219. North Shore Hematology Oncology Associates ("NSHOA") is a member of the ION GPO, and it is located in East Setauket, New York. NSHOA bills $30 million in drug purchases annually. Approximately 40% of NSHOA's revenues were Government Program reimbursements, so reimbursement dollars are critical to profitability.

220. Fully aware of NSHOA's dependency on high Government Program reimbursements for its profitability, Lilly used the volumetric cash rebate incentives under the ION GPO contract to persuade NSHOA that it should purchase and prescribe greater quantities of Gemzar® and Alimta® *not* based on their FDA-approved indications, but based instead on the facts that doing so would lead to (i) a greater profit margin in terms of dollars on each

prescription, and (ii) a greater cash rebate (generally ranging from 3% to 7%) from Lilly. This improper, off-label persuasion occurred in multiple meetings between NSHOA and Lilly's B2B Associates (*e.g.*, Rob Rubin, Alan McWilliams) and Lilly's sales representative (Relator Turano) acting at the specific direction of District Manager Polkowitz. Sometimes, NSHOA principals (*e.g.,* Harold Woodinsky, Mark Levin, E. Roy Berger) attended these meetings, as did DM Polkowitz.

221. This is precisely the scenario that played out when, for example, in January 2006, Lilly B2B Associate Rob Rubin encouraged Relator Turano to promote Alimta® off-label to NSHOA as part of a GPO Pull-Through program. During a joint sales call by Relator Turano and B2B Associate Rubin, they actively promoted Alimta® for off-label indications on the basis that, with additional prescriptions, NSHOA would exceed its GPO rebate objectives for that quarter and thus receive greater rebates. Relator Turano participated in this promotion because he understood that he was required by B2B Associate Rubin and DM Polkowitz to do so, and that his job would be in jeopardy if he refused.

222. On May 23, 2006, Rubin again accompanied Relator Turano on a sales call to NSHOA. Again, Relator Turano believed he had no choice in the matter if he wanted to keep his job, and again they encouraged NSHOA's physicians to prescribe Alimta® and Gemzar® in greater quantities, including for off-label uses, in order to achieve greater rebates through the ION GPO contract.

223. Indeed, throughout 2006, Relator Turano repeatedly met with and was instructed by B2B Associate Rubin to achieve his sales performance and drug volume objectives for Alimta® and Gemzar® by leveraging the tiered volume discounts provided by the ION contract to

persuade NSHOA to prescribe more Alimta® and Gemzar®, including for off-label uses. Relator Turano believed he would be subject to discipline or termination if he refused.

224. Not long thereafter, on August 30, 2007, B2B Associate McWilliams accompanied Relator Turano on sales calls to George Calcanes (North Shore Hematology Oncology Associates) and Linda Bennis (Practice Manager and Principal Drug Purchasing Agent at Hematology Oncology Associates of Western Suffolk, *see* discussion *infra*) in order to aggressively sell and incentivize those practices to use Alimta® and Gemzar®, including for off-label uses, in order for them to meet and exceed their GPO contract rebate objectives. As with the sales calls in which he was accompanied by Mr. Rubin, Relator understood that he had no choice in the matter. Mr. McWilliams conducted a follow-up meeting with Ms. Bennis on December 10, 2007 for the purpose of monitoring her organization's progress toward meeting and exceeding its GPO contract rebate objectives.

225. Recently, NSHOA's Calcanes has expressed to Relator Turano significantly negative feelings about Lilly's tactics in promoting cash rebates as an incentive to prescribe greater quantities of Gemzar® and Alimta®. According to Calcanes, Lilly refused to pay NSHOA a rebate that it believed it was entitled to because, according to Calcanes, Lilly claimed the rebate would be paid only if all participants in the ION GPO met contract objectives.

226. At some point in 2009, NSHOA banned Lilly oncology from having any contact with the practice or its providers.

2. Hematology Oncology Associates of Western Suffolk

227. Hematology Oncology Associates of Western Suffolk ("HOAWS") is a member of the McKesson/Onmark GPO, and it is located in Bay Shore, New York. As with NSHOA,

Lilly understood that approximately 40% of HOAWS' revenues were Government Program reimbursements, so reimbursement dollars are critical to profitability.

228. The Onmark GPO contract is similar to the ION GPO contract, as is the manner in which Lilly improperly uses the reimbursement and rebate incentives described *supra* to encourage Onmark GPO members to prescribe ever-increasing quantities of Gemzar® and Alimta® off-label.

229. For example, on or about July 2, 2007, Alan McWilliams (who had replaced Rob Rubin as Lilly's B2B Associate assigned to work with Relator Turano's sales targets) and Lilly's B2B Director, Deidre Winkle, convened a telephone conference with Relator Turano in which they directed him to prepare a business plan focused on meeting the Onmark GPO contract's rebate objectives by aggressively promoting sales of Alimta® and Gemzar® to HOAWS, including for off-label uses. Relator Turano had no choice in the matter if he wanted to keep his job.

230. Following these explicit instructions, Relator Turano attended multiple sales meetings with HOAWS, both in person and by telephone, that also included B2B Associate McWilliams, HOAWS Practice Manager Linda Bennis, HOAWS principal partner Dr. Paul Hyman and Lilly DM Michael Polkowitz. During these meetings, Lilly actively promoted the off-label use of Gemzar® and Alimta®, regardless of the limits of their FDA-approved labels, on the basis that such prescriptions would increase HOAWS' bottom-line profitability. By virtue of DM Polkowitz's presence on the call, Relator Turano understood that he should keep his concerns to himself unless he wanted to put his job in jeopardy.

3. Bogus GPO Educational Programs that Promote Off-Label Use of Gemzar® and/or Alimta®

231. Lilly also improperly coordinated with several GPOs to organize bogus "educational" programs that were designed to encourage increased, off-label overuse of Lilly's drugs, including Alimta®, in order to personally profit the prescribing physicians and their practices. In fact, Lilly built these programs into its contracts with the GPOs, requiring that Lilly be permitted to fund and promote the programs for participating oncology practices.

232. These programs are not purely "educational," but are primarily promotional in nature. Typically, the GPO provides a speaker, usually a medical oncologist paid to participate by Lilly, and the speaker makes a presentation to GPO members about how they could best use Alimta® in their practices. At Lilly, these promotional presentations focused on off-label uses of Alimta®, and they were intended to further Lilly's GPO Pull Through objectives. Thus, they were illegal.

233. Drs. Mark Socinski and Roman Perez-Soler, discussed *supra*, are two physicians who delivered separate, paid, off-label pro-Alimta® presentations to the physicians of Hematology Oncology Associates of Western Suffolk, and it is believed that those presentations were delivered under this GPO framework. Like virtually every oncology practice, a significant percentage of HOAWS' patients are Medicare beneficiaries. Following these presentations, HOAWS' utilization of Alimta® (and hence its use to treat Medicare beneficiaries) increased dramatically.

234. That these GPO presentations were promotional in nature, and not intended to be balanced, is confirmed by the fact that Lilly instructed its sales representatives, including Relator Turano, to promote the off-label uses discussed in the presentations *as soon as possible* after the presentations had concluded. Plainly, these presentations were intended to work "hand-in-glove" with Lilly's overall GPO Pull Through initiative. Indeed, in Relator Turano's 2008 Performance

Management review, for example, he was praised for developing, as part of his "GPO Pull Through" objective, a "strong relationship and communication and follow up with B2B Account Manger [sic], Alan McWilliams, in order to coordinate ION, USO initiatives with key accounts Hem/Onc Associates of Western Suffolk and North Shore Hem/Onc Associates."

235. Lilly's use of the GPO deals to drive off-label sales is ongoing. In April 2010, Lilly specifically targeted Howard Levine of Queens Medical Associates ("QMA") in Fresh Meadows, New York for an additional sales push in part because QMA is a potential high-volume prescriber of Alimta®, but more so because Levine plays a significant role on the OnMark GPO Steering Committee.

236. And, in May 2010, Randy Maloziec, Lilly's Account Manager for Oncology Physician Networks, confirmed that Lilly had proposed 25 physician practices to Onmark for potential "P2P Intervention" programs. Though not all were guaranteed to receive a program (since only 15 had been contracted), Lilly expressly intended that its sales representatives would coordinate their promotional activities around those programs.

237. As was intended by Lilly, this arrangement has led physicians to (i) switch patients from the less expensive and on-label use of paclitaxel to the more expensive and off-label branded Alimta®; (ii) initiate patients on the more expensive and off-label Alimta® therapy; and (iii) inappropriately increase the dosing of Alimta®.

C. LILLY HAS IMPROPERLY BUNDLED AND PROMOTED GEMZAR® WITH ALIMTA® UNDER ITS GPO CONTRACTS IN ORDER TO AVOID LOSING MARKET SHARE

238. Beginning as early as 2004, when Alimta® was approved for the second-line treatment of NSCLC, Lilly implemented a strategy to transition Gemzar® prescribers to Alimta®

(for both first- and second-line use), in anticipation of Gemzar®'s loss of market exclusivity. Lilly called this strategy to cannibalize Gemzar® sales "Surpass Gemzar®."

239. Initially, the Surpass Gemzar® strategy was rolled out to the sales force as a means of increasing revenue due to the fact that Alimta® was (and remains) more expensive than Gemzar®. But, the Surpass Gemzar® strategy has taken a further twist as the end of Gemzar®'s patent exclusivity quickly approaches.

240. Lilly knows that revenue from sales of Gemzar® will fall off dramatically when it loses patent protection at the end of this year and soon thereafter becomes available in generic form. Lilly thus has sought to retain its Gemzar® market share – or at least the revenues it has enjoyed to date – by "bundling" Gemzar® with Alimta® under the GPO agreements, and telling healthcare professionals that their increased utilization of Gemzar® today will count towards their achievement of greater volume discounts on Alimta® going forward. The off-label Gemzar®/docetaxel combination therapy has been a principal focus of that sales pitch. In this way, Lilly not only has used financial incentives to prompt off-label use of Gemzar®, but it also has leveraged that off-label use to prompt off-label sales of Alimta® going forward.

D. THE FRAUDULENT MARKETING SCHEME HAS BEEN A FINANCIAL SUCCESS FOR LILLY

241. The financial success of Lilly's Fraudulent Marketing Scheme was in evidence when Lilly disclosed that it increased sales of Alimta® by 57% in Q1 2010 (over the same period in 2009) and by 43% in Q2 2010 (over the same period in 2009). *See* Press Release, Eli Lilly & Company, *Lilly Reports First-Quarter 2010 Results* (April 19, 2010) (on file with author); Press Release, Eli Lilly & Company, *Lilly Reports Strong Second-Quarter 2010 Results* (July 22, 2010) (on file with author).

X. LILLY'S FRAUDULENT MARKETING SCHEME CAUSED THE SUBMISSION OF FALSE CLAIMS TO FEDERAL PROGRAMS AND QUI TAM STATES.

242. Lilly's Fraudulent Marketing Scheme served its intended purpose, as it has induced doctors to write off-label prescriptions for Gemzar® and Alimta®, and as it has induced the submission of claims for reimbursement of those prescriptions by Government Programs. And, the Government Programs did, in fact, reimburse those claims for off-label uses.

243. At least in part as a result of Lilly's illegal sales and marketing practices, Gemzar® and Alimta® have been heavily used for the treatment of Medicaid, Medicare Part B, Medicare Part D, and other Government Program participants.

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1))

244. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

245. Defendant knowingly presented and caused to be presented to the Government false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1).

246. As a result of Defendant's actions as set forth above in this Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2))

247. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

248. Defendant knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of a false or fraudulent claims, thereby

causing false or fraudulent claims for payment to actually be paid or approved, in violation of 31 U.S.C. § 3729(a)(2).

249. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Alimta® prescribed to patients enrolled in Federal Programs.

250. As a result of Defendant's actions as set forth above in this Complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3))

251. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

252. As detailed above, Defendant knowingly conspired with the various health care professionals identified and described herein to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2). Defendant and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

253. As a result of Defendant's actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of California False Claims Act)

254. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

255. This is a civil action brought by Relator on behalf of the State of California against Defendant under the California False Claims Act, CAL. CODE § 12652(c).

256. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of California or its political subdivisions false or fraudulent claims for payment, in violation of CAL. CODE § 12651(a)(1).

257. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of CAL. CODE § 12651(a)(2).

258. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of CAL. CODE § 1265 1 (a)(7).

259. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

260. As a result of Defendant's actions as set forth above, the State of California, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT V
(Violation of Colorado Medicaid False Claims Act)

261. Relator incorporated herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

262. This is a civil action brought by Relator on behalf of the State of Colorado against Defendant under the State of Colorado False Claims Act, COLO. REV. STAT. § 25.5-4-304.

263. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of COLO. REV. STAT. § 25.5-4-305(a).

264. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of COLO. REV. STAT. § 25.5-4-305(b).

265. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado or one of its political subdivisions, in violation of COLO. REV. STAT. § 25.5-4-305(f).

266. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

267. As a result of Defendant's actions, as set forth above, the State of Colorado or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VI
(Violation of Connecticut False Claims Act)

268. Relator incorporated herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

269. This is a civil action brought by Relator on behalf of the State of Connecticut against Defendant under the Connecticut False Claims Act, 2009 Conn. Pub. Acts No. 09-5.

270. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of 2009 Conn. Pub. Acts No. 09-5 § 2(a)(1).

271. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of Conn. Pub. Acts No. 09-5 § 2(a)(2).

272. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions in violation of Conn. Pub. Acts No. 09-5 § 2(a)(1).

273. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

274. As a result of Defendant's actions as set forth above, the State of Connecticut, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT VII
(Violation of Delaware False Claims and Report Act)

275. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

276. This is a civil action brought by Relator on behalf of the Government of the State of Delaware against Defendant under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

277. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, directly or indirectly, to an officer or employee of the Government of the State of Delaware false

or fraudulent claims for payment or approval, in violation of DEL. CODE ANN. tit. 6, §1201 (a)(1).

278. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved, in violation of DEL. CODE ANN. tit. 6, §1201(a)(2).

279. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the Government of Delaware, in violation of DEL. CODE ANN. tit. 6, § 120l(a)(7).

280. The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

281. As a result of Defendant's actions, the Government of the State of Delaware has been, and may continue to be, severely damaged.

COUNT VIII
(Violation of District of Columbia False Claims Act)

282. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

283. This is a civil action brought by Relator in the name of the District of Columbia against Defendant under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(a).

284. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, a false or fraudulent claim for payment or approval, in violation of D.C. CODE ANN. § 2-308.14(a)(l).

285. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records and/or statements to get false claims paid or approved by the District, in violation of D.C. CODE ANN. § 2-308.14(a)(2).

286. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, in violation of D.C. CODE ANN. § 2-308.14(a)(7).

287. The District of Columbia, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

288. As a result of Defendant's actions, as set forth above, the District of Columbia has been, and continues to be, severely damaged.

COUNT IX
(Violation of Florida False Claims Act)

289. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

290. This is a civil action brought by Relator on behalf of the State of Florida against Defendant under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

291. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Florida or one of its agencies false or fraudulent claims for payment or approval, in violation of FLA. STAT. ANN. § 68.082(2)(a).

292. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(b).

293. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082 (2)(g).

294. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

295. As a result of Defendant's actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT X
(Violation of Georgia Medicaid False Claims Act)

296. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

297. This is a civil action brought by Relator, in the name of the State of Georgia, against Defendant pursuant to the State of Georgia Medicaid Fraud False Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

298. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a

false statement or misrepresentation of material fact on an application for any benefit or payment under the Georgia Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

299. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of GA. CODE ANN. § 49-4-168 (2007).

300. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of GA. CODE ANN. § 49-4-168 (2007).

301. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of GA. CODE ANN. § 49-4-168 (2007).

302. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

303. As a result of Defendant's actions, as set forth above, the State of Georgia or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XI
(Violation of Hawaii False Claims Act)

304. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

305. This is a civil action brought by Relator on behalf of the State of Hawaii and its political subdivisions against Defendant under the State of Hawaii's False Claims Act -False Claims to the State, HAW. REV. STAT. § 661-25.

306. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of HAW. REV. STAT. § 61-21(a)(l).

307. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(2).

308. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(7).

309. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

310. As a result of Defendant's actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Indiana False Claims and Whistleblower Protection Act)

311. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

312. This is a civil action brought by Relator on behalf of the State of Indiana against Defendant under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

313. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(l).

314. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain payment or approval of false claims by the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(2).

315. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(6).

316. The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

317. As a result of Defendant's actions, as set forth above, the State of Indiana has been, and may continue to be, severely damaged.

COUNT XIII
(Violation of Illinois Whistleblower Reward and Protection Act)

318. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

319. This is a civil action brought by Relator on behalf of the State of Illinois against Defendant under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. 175/4(b).

320. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois or a member of the Illinois National Guard a false or fraudulent claim for payment or approval, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(I).

321. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(2).

322. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(7).

323. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

324. As a result of Defendant's actions, as set forth above, the State of Illinois has been, and may continue to be, severely damaged.

COUNT XIV
(Violation of Louisiana Medical Assistance Programs Integrity Law)

325. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

326. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs against Defendant under the State of Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. § 46:439.1.

327. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

328. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of LA. REV. STAT. § 46:438.3(B).

329. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of LA. REV. STAT, § 46:438.3 (D).

330. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by

Defendant, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendant's claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

331. As a result of Defendant's actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Massachusetts False Claims Act)

332. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

333. This is a civil action brought by Relator on behalf of the Commonwealth of Massachusetts against Defendant under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

334. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MASS. LAWS ANN, ch. 12, § 5B(1).

335. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the

Commonwealth of Massachusetts or its political subdivisions in violation of MASS. LAWS ANN. ch. 12, § 5B(2).

336. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or one of its political subdivisions, in violation of MASS. LAWS ANN. ch. 12, § 5B(8).

337. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

338. As a result of Defendant's actions, as set forth above, the Commonwealth of Massachusetts or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Michigan Medicaid False Claims Act)

339. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

340. This is a civil action brought by Relator in the name of the State of Michigan against Defendant under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).

341. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of MICH. COMP. LAWS. SERV. § 400.603(1).

342. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit, in violation of MICH. COMP. LAWS. SERV. § 400.603(2).

343. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf Defendant has applied for or is receiving a benefit with intent to obtain a benefit to which Defendant are not entitled or in an amount greater than that to which Defendant are entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

344. Defendant, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly presented or made or caused to be presented or made, and may still be presenting or causing to be presented a false claim under the social welfare act, Act No.

280 of the Public Acts of 1939, as amended, in violation of MICH. COMP. LAWS. SERV. § 400.607(1).

345. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

346. As a result of Defendant's actions, as set forth above, the State of Michigan or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Minnesota False Claims Act)

347. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

348. This is a civil action brought by Relator on behalf of the State of Minnesota against Defendant under the State of Minnesota False Claims Act, Minn. Stat. § 15C.01.

349. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

350. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of Minn. Stat. § 15C.02(a)(2).

351. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota or one of its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

352. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

353. As a result of Defendant's actions, as set forth above, the State of Minnesota or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Montana False Claims Act)

354. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

355. This is a civil action brought by Relator on behalf of the State of Montana against Defendant under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

356. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(l)(a).

357. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

358. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana or one of its political subdivisions, in violation of MONT. CODE ANN. § 17-8-403(l)(g).

359. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

360. As a result of Defendant's actions, as set forth above, the State of Montana or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of New Hampshire Medicaid False Claims Act)

361. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

362. This is a civil action brought by Relator on behalf of the State of New Hampshire against Defendant under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

363. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

364. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a fake claim paid or approved, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(b).

365. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire or one of its political subdivisions, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(e).

366. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

367. As a result of Defendant's actions, the State of New Hampshire or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of New Jersey False Claims Act)

368. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

369. This is a civil action brought by Relator, in the name of the State of New Jersey, against Defendant pursuant to the State of New Jersey Fraud False Claims Act, N.J. STAT. ANN. § 265 (2007), *et seq.*

370. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the New Jersey Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

371. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of N.J. STAT. ANN. § 265 (2007).

372. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or

quantity than is due or when no benefit or payment is authorized, in violation of N.J. STAT. ANN. § 265 (2007).

373. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of N.J. STAT. ANN. § 265 (2007).

374. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

375. As a result of Defendant's actions, as set forth above, the State of New Jersey or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXI
(Violation of New Mexico Medicaid False Claims Act)

376. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

377. This is a civil action brought by Relator on behalf of the State of New Mexico against Defendant under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

378. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

379. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may be continuing to present or causing to be presented a claim for payment under the Medicaid program that is not authorized or is not eligible for benefit under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4B.

380. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved, in violation of N.M. STAT. ANN. § 27-14-4C.

381. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico or one of its political subdivisions, in violation of N.M. STAT. ANN. § 27-14-4E.

382. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

383. As a result of Defendant's actions, as set forth above, the State of New Mexico or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII
(Violation of New York False Claims Act)

384. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

385. This is a civil action brought by Relator on behalf of the State of New York against Defendant under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

386. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

387. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

388. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York or one of its political subdivisions, in violation of N.Y.CLS St. Fin. § 189(g).

389. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

390. As a result of Defendant's actions, as set forth above, the State of New York or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of Nevada Submission of False Claims to State or Local Government Act)

391. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

392. This is a civil action brought by Relator on behalf of the State of Nevada against Defendant under the State of Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. ANN. § 357.080(1)

393. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(l)(a).

394. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

395. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada or one of its political subdivisions, in violation of NEV. REV. STAT. ANN. § 357.040(1)(g).

396. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

397. As a result of Defendant's actions, as set forth above, the State of Nevada or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of North Carolina False Claims Act)

398. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

399. This is a civil action brought by Relator on behalf of the State of North Carolina against Defendant under the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605.

400. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.C. GEN. STAT. § 1-607(a)(1).

401. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the State of North Carolina or its political subdivisions in violation of N.C. GEN. STAT. § 1-607(a)(2).

402. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina or one of its political subdivisions, in violation of N.C. GEN. STAT. § 1-607(a)(7).

403. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

404. As a result of Defendant's actions, as set forth above, the State of North Carolina or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of Oklahoma Medicaid False Claims Act)

405. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

406. This is a civil action brought by Relator, in the name of the State of Oklahoma, against Defendant pursuant to the State of Oklahoma Medicaid Fraud False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

407. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Oklahoma Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

408. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

409. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

410. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2007).

411. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

412. As a result of Defendant's actions, as set forth above, the State of Oklahoma or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of Rhode Island False Claims Act)

413. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

414. This is a civil action brought by Relator, in the name of the State of Rhode Island, against Defendant pursuant to the State of Rhode Island Fraud False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

415. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a

false statement or misrepresentation of material fact on an application for any benefit or payment under the Rhode Island Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

416. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

417. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

418. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-1 (2008).

419. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

420. As a result of Defendant's actions, as set forth above, the State of Rhode Island or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of Tennessee Medicaid False Claims Act)

421. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

422. This is a civil action brought by Relator in the name of the State of Tennessee against Defendant under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

423. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee a claim for payment under the Medicaid program knowing it was false or fraudulent, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(A).

424. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(B).

425. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, relative to the Medicaid program, with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(D).

426. The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

427. As a result of Defendant's actions, as set forth above, the State of Tennessee has been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Texas Human Resources Code, Medicaid Fraud Prevention Chapter)

428. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

429. This is a civil action brought by Relator in the name of the State of Texas against Defendant under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

430. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a

false statement or misrepresentation of material fact on an application for a contract, benefit or payment under a Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(1).

431. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact that is intended to be used, and has been used, to determine a person's eligibility for a benefit or payment under the Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(2).

432. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of TEX. HUM. RES. CODE § 36.002(4)(B).

433. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made a claim under the Medicaid program for a service or product that was inappropriate, in violation of TEX. HUM. RES. CODE § 36.002(7)(C),

434. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

435. As a result of Defendant's actions, as set forth above, the State of Texas, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Virginia Fraud Against Taxpayers Act)

436. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

437. This is a civil action brought by Relator on behalf of the Commonwealth of Virginia against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq.*

438. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval, in violation of VA. CODE ANN. § 8.01-216.3(A)(1).

439. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(2).

440. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(7).

441. The Commonwealth of Virginia, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

442. As a result of Defendant's actions, as set forth above, the Commonwealth of Virginia, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Wisconsin False Claims for Medical Assistance Act)

443. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

444. This is a civil action brought by Relator on behalf of the State of Wisconsin against Defendant under the State of Wisconsin False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

445. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the state, a false or fraudulent claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(a) (2007).

446. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(b).

447. The State of Wisconsin, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

448. As a result of Defendant's actions, as set forth above, the State of Wisconsin, its political subdivisions or the Department has been, and may continue to be, severely damaged.

WHEREFORE, Relator prays for judgment against Defendant as follows:

A. That Defendant be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729, et seq., CAL. CODE § 12650, et seq., COLO. REV. STAT. § 25.5-4-304 et seq., 2009 CONN. PUB. ACTS NO. 09-5, et seq., DEL. CODE ANN. tit. 6, § 1201, et seq., D.C. CODE ANN. § 2-308.13, et seq., FLA. STAT. ANN. § 68.081, et seq., GA. CODE ANN. § 49-4-168, et seq., HAW. REV. STAT. § 661-21, et seq., 740 ILL. COMP. STAT. ANN. § 1751, et seq., IND. CODE ANN. § 5-11-5.5, et seq., LA. REV. STAT. § 437.1, et seq., MASS. LAWS ANN. Ch. 12, §5A, et seq., MICH. COMP. LAWS SERV. § 400.601, et seq., MINN. STAT. § 15C.01 et seq., MONT. CODE ANN. § 17-8-401, et seq., NEV. REV. STAT. ANN. § 357.010, et seq., N.H. REV. STAT. ANN. § 167:61-b, et seq., N.J. STAT ANN. § 265, et seq., N.M. STAT. ANN. § 27-14-1, et seq., N.Y. CLS ST. FIN. § 187, et seq., N.C. GEN. STAT. § 1-605, et. seq., OKLA. STAT. tit. 63, § 5053, et seq., R.I. GEN. LAWS § 9-1,1-1, et seq., TENN. CODE ANN. § 71-5-181, et seq., TEX. HUM. RES. CODE

§ 36.001, et seq., VA. CODE ANN. § 8.01-216.1, et seq., and WIS. STAT. § 20.931 (2007), et seq.

B. That judgment be entered in Relator's favor and against Defendant in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator Weathersby be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), CAL. CODE § 12650, et seq., COLO. REV. STAT. § 25.5-4-304 et seq., 2009 CONN. PUB. ACTS NO. 09-5 § 5 (e), DEL. CODE ANN. tit. 6, § 1201, et seq., D.C. CODE ANN. § 2-308.13, et seq., FLA. STAT. ANN. § 68.081, et seq., GA. CODE ANN. § 49-4-168, et seq., HAW. REV. STAT. § 661-21, et seq., 740 ILL. COMP. STAT. ANN. § 1751, et seq., IND. CODE ANN. § 5-11-5.5, et seq., LA. REV. STAT. § 437.1, et seq., MASS. LAWS ANN. Ch. 12, §5A, et seq., MICH. COMP. LAWS SERV. § 400.601, et seq., MINN. STAT. § 15C.01 et seq., MONT. CODE ANN. § 17-8-401, et seq., NEV. REV. STAT. ANN. § 357.010, et seq., N.H. REV. STAT. ANN. § 167:61-b, et seq., N.J. STAT ANN. § 265, et seq., N.M. STAT. ANN. § 27-14-1, et seq., N.Y. CLS ST. FIN. § 187, et seq., N.C. GEN. STAT. § 1-605, et. seq., OKLA. STAT. tit. 63, § 5053, et seq., R.I. GEN. LAWS § 9-1,1-1, et seq., TENN. CODE ANN. § 71-5-181, et seq., TEX. HUM. RES. CODE § 36.001, et seq., VA. CODE ANN. § 8.01-216.1, et seq., and WIS. STAT. § 20.931 (2007), et seq.

D. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars ($10,000) per claim as provided by CAL. CODE § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Government of the State of Colorado multiplied as provided for in COLO. REV. STAT. § 25.5-4-305, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Colorado Medicaid False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Colorado for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Government of the State of Connecticut multiplied as provided for in 2009 Conn. Pub. Acts No. 09-5 § 2(b), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Pub. Acts No. 09-5 § 2(b), to the extent such multiplied penalties shall fairly compensate the Government of the State of Connecticut for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Government of the State of Delaware multiplied as provided for in DEL. CODE ANN. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five-hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Delaware False Claims and Reporting Act, as provided by DEL. CODE ANN. tit. 6, § 1201(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Delaware for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. CODE ANN. § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. CODE ANN. § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in FLA. STAT. ANN. § 68.082, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by FLA. STAT. ANN. § 68.082, to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in GA. CODE ANN. § 49-4-168, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent of the proceeds per claim as provided by GA. CODE ANN. § 49-4-168.2, to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in HAW. REV. STAT. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by HAW. REV. STAT. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Indiana, multiplied as provided for in IND. CODE ANN. § 5-11-5.5-2, plus a civil penalty of at least five thousand dollars ($5,000) as provided by IND. CODE ANN. § 5-11-5.5-2, to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 ILL. COMP.

STAT, ANN. 175/3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000), and the costs of this civil action brought to recover such damages and penalty, as provided by 740 ILL. COMP. STAT. ANN. 175/3(a), to the extent such multiplied penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in LA. REV. STAT § 438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by LA. REV. STAT § 438.6(B)(I), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by LA. REV. STAT § 438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by LA. REV. STAT. § 438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator's favor and against Defendant for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, 65B, multiplied as provided for in MASS. LAWS ANN. ch. 12,

§ 5B, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to MASS. LAWS ANN, ch. 12, 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in MICH. COMP. LAWS SERV. §§ 400.603-400.606, 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Government of the State of Minnesota multiplied as provided for in MINN. STAT. § 15C.02(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Minnesota False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Minnesota for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in

MONT. CODE ANN. § 17-8-403(2), multiplied as provided for in MONT. CODE ANN. § 17-8-403(2), plus a civil penalty of up to ten thousand dollars ($10,000) for each false claim, pursuant to MONT. CODE ANN. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator's favor and against Defendant for restitution to the State of New Hampshire or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:6111, multiplied as provided for in N.H. REV. STAT. ANN. § 167:61II, plus a civil penalty of two thousand dollars ($2,000) for each false claim, pursuant to REV. STAT. ANN. § 167:61II, to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. STAT. ANN. § 265, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by N.J. STAT. ANN. § 265, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator's favor and against Defendant for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.M. STAT. ANN. § 27-14-4, multiplied as provided for in N.M. STAT. ANN. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after fill discovery;

V. That judgment be entered in Relator's favor and against Defendant for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.Y. CLS St. Fin. § 189.1., multiplied as provided for in N.Y. CLS St. Fin. § 189.1., plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. CLS St. Fin. § 189.l., to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in NEV. REV. STAT. ANN. 357.040, multiplied as provided for in NEV. REV. STAT. ANN. § 357.040(1), plus a civil penalty of not less than two thousand dollars ($2,000) or more than ten thousand dollars ($10,000) for each act, pursuant to NEV. REV. STAT. ANN. § 357.040, to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken

by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator's favor and against Defendant for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in N.C. GEN. STAT. § 1-605, multiplied as provided for in N.C. GEN. STAT. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. GEN. STAT. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in OKLA. STAT. tit. 63, § 5053, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by OKLA. STAT. tit. 63, § 5053.4, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. GEN. LAWS § 9-1,1-1, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by R.I. GEN. LAWS § 9-1,1-4, to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or

its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in TENN. CODE ANN. § 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) pursuant to TENN. CODE ANN. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(l), multiplied as provided for in TEX. HUM. RES. CODE § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to TEX. HUM. RES. CODE § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to TEX. HUM. RES. CODE § 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting

from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in VA. CODE ANN. § 8.01-216.3(A), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by VA. CODE ANN. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in WIS. STAT. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by WIS. STAT. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

EE. That Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

FF. That judgment be granted for Relator against Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

GG. That Relator be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.

Dated: August 27, 2010

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